No. 01-188

IN THE
Supreme Court of the United States

Supreme Court, U.S.
FILED
SEP 20 2002
CLERK

PHARMACEUTICAL RESEARCH & MANUFACTURERS OF AMERICA,

Petitioner,

v.

KEVIN CONCANNON, COMMISSIONER, MAINE DEPARTMENT OF HUMAN SERVICES, AND G. STEVEN ROWE, ATTORNEY GENERAL OF MAINE,

Respondents.

On Writ of Certiorari to the United States Court of Appeals for the First Circuit

JOINT APPENDIX

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September 20, 2002

PETITION FOR CERTIORARI FILED JULY 31, 2001
CERTIORARI GRANTED JUNE 28, 2002

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42 U.S.C. § 1396r-8 (in pertinent part) ..... App. 73-84

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MAINE DISTRICT COURT

1:2000cv00157

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA,

Plaintiff,

v.

COMMISSIONER, MAINE DEPARTMENT OF HUMAN SERVICES, et al.,

Defendants.

DOCKET ENTRIES

DATE	NO.	PROCEEDINGS
8/10/00	1	COMPLAINT filed; FILING FEE $ 150 RECEIPT # 41094 (Service of Process Deadline 12/8/00) (hdj) [Entry date 08/11/00]
8/10/00	2	MOTION by PHARMACEUTICAL RESEA for Leave to File memo in excess of page limits (hdj) [Entry date 08/11/00]
8/10/00	3	MOTION with memorandum in support by PHARMACEUTICAL RESEA for Preliminary Injunction (hdj) [Entry date 08/11/00]
8/10/00	4	AFFIDAVIT of Russel A. Bantham (hdj) [Entry date 08/11/00]
8/10/00	5	AFFIDAVIT of Richard A. Feldman (hdj) [Entry date 08/11/00]
8/10/00	6	AFFIDAVIT of George Bilyk (hdj) [Entry date 08/11/00]

DATE	NO.	PROCEEDINGS
8/10/00	7	AFFIDAVIT of Thomas M. McPhillips (hdj) [Entry date 08/11/00]
8/10/00	8	AFFIDAVIT of Judith L. Tempel (hdj) [Entry date 08/11/00]
8/10/00	9	AFFIDAVIT of David Moules (hdj) [Entry date 08/11/00]
8/10/00	10	AFFIDAVIT of Scott Howell, M.D. (hdj) [Entry date 08/11/00]
8/10/00	—	SUMMONS(ES) issued for HS, ME COMMN, ATTORNEY GENERAL, ME (hdj) [Entry date 08/11/00]
8/11/00	—	CORPORATE DISCLOSURE STATEMENT per Local Rule 83.7 by PHARMACEUTICAL RESEA (hdj)
8/11/00	—	Pro Hac Vice Certificate for PHARMACEUTICAL RESEA by DANIEL M. PRICE, ALLEN S. RUGG (hdj)
8/11/00	—	ENDORSEMENT on Motion granting [2-1] motion for Leave to File memo in excess of page limits (/s/For the Court, Harriett D. Jefferson, Deputy Clerk) cc: cnsl (hdj)
8/16/00	—	RETURN of Service Executed as to HS, ME COMMN, ATTORNEY GENERAL, ME 8/11/00 Answer due on 8/31/00 for ATTORNEY GENERAL, ME, for HS, ME COMMN (jgw)
8/23/00	—	MOTION during telephone conference by HS, ME COMMN, ATTORNEY GENERAL, ME to Extend Time to file answer and response to preliminary injunction motion (jgw)

DATE	NO.	PROCEEDINGS
8/23/00	11	REPORT of Conference of Counsel granting in part [0-0] oral motion to Extend Time to file answer and response to preliminary injunction motion, reset Answer deadline to 9/11/00 for ATTORNEY GENERAL, ME, for HS, ME COMMN, Response to Motion reset to 9/11/00 for ATTORNEY GENERAL, ME, for HS, ME COMMN for [3-1] motion for Preliminary Injunction (signed by MAG. JUDGE MARGARET J. KRAVCHUK) cc: cnsl (jgw) PORTLD STNDRD
9/11/00	12	MOTION by HS, ME COMMN, ATTORNEY GENERAL, ME for Leave to File response in excess of page limits (jgw)
9/11/00	13	RESPONSE by HS, ME COMMN, ATTORNEY GENERAL, ME to [3-1] motion for Preliminary Injunction ; Reply to Response due 9/21/00 for PHARMACEUTICAL RESEA (jgw)
9/11/00	14	AFFIDAVIT of Kevin Concannon (jgw)
9/11/00	15	AFFIDAVIT of Timothy S. Clifford, M.D. (jgw)
9/11/00	16	AFFIDAVIT of Buritt Richardson, Jr., M.D. (jgw)
9/11/00	17	ANSWER to Complaint by HS, ME COMMN, ATTORNEY GENERAL, ME (jgw)

DATE	NO.	PROCEEDINGS
9/12/00	—	ENDORSEMENT on Motion granting [12-1] motion for Leave to File response in excess of page limits (signed by Walentine, DC for JUDGE D. B. HORNBY) cc: cnsl (jgw)
9/20/00	18	Letter MOTION by HS, ME COMMN, ATTORNEY GENERAL, ME for Order granting protection from hearing or o/a from 9/27 to 10/13 (err)
9/20/00	—	Motion(s) taken under advisement: [18-1] motion for Order granting protection from hearing or o/a from 9/27 to 10/13 under advisement (err)
9/21/00	—	Pro Hac Vice Certificate for PHARMACEUTICAL RESEA by KATHLEEN M. SULLIVAN (jgw)
9/21/00	19	MOTION by PHARMACEUTICAL RESEA for Leave to File reply brief in excess of page limits (jgw)
9/21/00	20	REPLY by PHARMACEUTICAL RESEA to response to [3-1] motion for Preliminary Injunction (jgw)
9/21/00	—	ENDORSEMENT on Motion granting [19-1] motion for Leave to File reply brief in excess of page limits (signed by Walentine, DC for JUDGE D. B. HORNBY) cc: cnsl (jgw)
9/21/00	21	MOTION by PHARMACEUTICAL RESEA for Hearing on [3-1] motion for Preliminary Injunction (jgw)

DATE	NO.	PROCEEDINGS
9/21/00	—	Motion(s) taken under advisement: [21-1] motion for Hearing on [3-1] motion for Preliminary Injunction under advisement (jgw)
9/26/00	22	Letter RESPONSE by PHARMACEUTICAL RESEA to [18-1] motion for Order granting protection from hearing or o/a from 9/27 to 10/13 ; Reply to Response due 10/6/00 for ATTORNEY GENERAL, ME, for HS, ME COMMN (jgw) [Entry date 09/27/00] PORTLD STNDRD
9/28/00	—	ENDORSEMENT on Motion granting [21-1] motion for Hearing on [3-1] motion for Preliminary Injunction, granting [18-1] motion for Order granting protection from hearing or o/a from 9/27 to 10/13, Motion Hearing Set Re: [3-1] motion for Preliminary Injunction set for 9:00 10/19/00 (signed by Deputy Clerk, Marie Cross for JUDGE D. B. HORNBY) cc: cnsl (mmc)
10/3/00	23	ORDER (re: the Hearing set for 10/19/00 on the Motion for Preliminary Injunction), set Telephone Conference for 3:30 10/17/00 (re: final hearing on the merits, factual disputes, etc.) (signed by JUDGE D. B. HORNBY) cc: cnsl (mmc)
10/17/00	—	Tele-conference re: held. The Court has determined that the parties will proceed on the Preliminary Injunction Argument only on 10/19/00. (Court Reporter: Pauline Terry) before JUDGE D. B. HORNBY (mmc) [Entry date 10/19/00]

DATE	NO.	PROCEEDINGS
10/19/00	—	Motion(s) taken under advisement: [3-1] motion for Preliminary Injunction under advisement (mmc)
10/19/00	—	MOTION Hearing held re: [3-1] motion for Preliminary Injunction before JUDGE D. B. HORNBY. Any further filings shall be filed by 10/23/00. (Court Reporter: Pauline Terry) (mmc)
10/20/00	24	TRANSCRIPT filed of HEARING ON #3, MOTION FOR PRELIMINARY INJUNCTION for dates of: 10/19/2000, held before Judge D. BROCK HORNBY (Court Reporter: PAULINE TERRY) (dw)
10/23/00	25	MOTION (no objection) by MAINE COUNCIL OF SEN, VIOLA QUIRION for Leave to File Brief of amicus curiae (mmc)
10/23/00	26	AFFIDAVIT of John Moran (mmc)
10/23/00	27	AFFIDAVIT of Viola Quirion (mmc)
10/23/00	28	BRIEF filed by MAINE COUNCIL OF SEN, VIOLA QUIRION (mmc)
10/23/00	29	BRIEF filed by HS, ME COMMN, ATTORNEY GENERAL, ME (mmc)
10/23/00	30	BRIEF filed by PHARMACEUTICAL RESEA (mmc) PORTLD STNDRD
10/26/00	31	ORDER granting by agreement [25-1] motion for Leave to File Brief of amicus curiae, granting [3-1] motion for Preliminary Injunction. The Commisioner is here by preliminarily enjoined from penalizing manufacturers, by placing their drugs on

DATE	NO.	PROCEEDINGS
		prior listing status, for refusing to negotiate or to pay a rebate to Maine's RX program. The Attorney General is hereby preliminarily enjoined from seeking to enforce the illegal profiteering portion of the statute against transactions that occur outside the State of Maine, even of the presciption drugs eventually end up and are ultimately purchased in Maine. So Ordered. (signed by JUDGE D. B. HORNBY) cc: cnsl (mmc)
11/9/00	32	NOTICE OF INTERLOCUTORY APPEAL of [31-1] order by HS, ME COMMN, ATTORNEY GENERAL, ME FILING FEE $ 105 RECEIPT # 41921 (bfa)
11/9/00	—	CERTIFICATE of Clerk (Form 83) Org docs #: 1-32 (bfa)
11/9/00	—	Certified and transmitted record on appeal to U.S. Court of Appeals: [32-1] interlocutory appeal by ATTORNEY GENERAL, ME, HS, ME COMMN (bfa)
11/13/00	33	MOTION with memorandum in support by VIOLA QUIRION, MICHELLE CAMPBELL, MAINE COUNCIL OF SEN, RICHARD DONAHUE to Intervene ; Response to Motion due 12/1/00 for ATTORNEY GENERAL, ME, for HS, ME COMMN, for PHARMACEUTICAL RESEA (mjl)
11/13/00	34	AFFIDAVIT of Viola Quirion (mjl)
11/13/00	35	AFFIDAVIT of Michelle Campbell (mjl)

DATE	NO.	PROCEEDINGS
11/13/00	36	AFFIDAVIT of John Moran (mjl)
11/13/00	37	AFFIDAVIT of Richard J. Donahue, M.D. (mjl)
11/22/00	38	MOTION with memorandum in support by VIOLA QUIRION, MICHELLE CAMPBELL, RICHARD DONAHUE to Extend Time to file a Notice of Appeal (mnm)
12/1/00	39	RESPONSE by PHARMACEUTICAL RESEA to [33-1] motion to Intervene ; Reply to Response due 12/11/00 for RICHARD DONAHUE, for MAINE COUNCIL OF SEN, for MICHELLE CAMPBELL, for VIOLA QUIRION (mnm)
12/4/00	—	USCA Case Number Re: interlocutory appeal USCA NUMBER: 00-2446 (jgw)
12/4/00	40	RESPONSE by HS, ME COMMN, ATTORNEY GENERAL, ME to [33-1] motion to Intervene-(The defendants do not object to the motion to intervene filed by the Maine Council of Senior Citizens, et al. We will not be filing a memorandum in response to that motion.) (mnm) [Entry date 12/06/00] PORTLD STNDRD
12/11/00	41	REPLY by VIOLA QUIRION, MICHELLE CAMPBELL, MAINE COUNCIL OF SEN, RICHARD DONAHUE to response to [33-1] motion to Intervene (dw)
12/11/00	—	Motion(s) taken under advisement: [33-1] motion to Intervene under advisement-(dw)

DATE	NO.	PROCEEDINGS
12/14/00	42	ORDER denying [33-1] motion to Intervene-For these reasons, the motion to intervene is Denied and the motion for extention of time to file a notice of appeal is Denied because I have denied the motion to intervene. No action is necessary on the motion to alter or amend judgment and to dismiss Count V of the plaintiffs complaint (signed by JUDGE D. B. HORNBY) cc: cnsl (mnm) [Entry date 12/15/00]
12/14/00	—	ENDORSEMENT on Motion denying [38-1] motion to Extend Time to file a Notice of Appeal-see order #42 dated 12/14/00-The motion to intervene is DENIED and the motion for extension of time to file a notice of appeal is DENIED because I have denied the motion to intervene. No action is necessary on the motion to alter or amend judgment and to dismiss Count V of the plaintiff's Complaint (signed by JUDGE D. B. HORNBY) cc: cnsl (mnm) [Entry date 12/19/00]
4/9/01	43	MOTION to Intervene by EDWIN D SCHINDLER on behalf of plaintiff ; Response to Motion due 4/30/01 for ATTORNEY GENERAL, ME, for HS, ME COMMN (jgw)
4/27/01	44	RESPONSE by PHARMACEUTICAL RESEA to [43-1] motion to Intervene by EDWIN D SCHINDLER on behalf of plaintiff ; Reply to Response due 5/8/01 for EDWIN D SCHINDLER (mlh)

DATE	NO.	PROCEEDINGS
4/30/01	45	RESPONSE by HS, ME COMMN, ATTORNEY GENERAL, ME to [43-1] motion to Intervene by EDWIN D SCHINDLER on behalf of plaintiff ; Reply to Response due 5/11/01 for EDWIN D SCHINDLER (mmc) [Entry date 05/01/01]
5/7/01	47	MOTION by EDWIN D SCHINDLER for Clarification of Page Limit Set by Local Rule 7(c) and, if necessary for Leave to File reply in excess of page limit; Response to Motion due 5729/01 for ATTORNEY GENERAL, ME, for HS, ME COMMN, for PHARMACEUTICAL RESEA (mlh)
5/7/01	48	REPLY by EDWIN D SCHINDLER to response to [43-1] motion to Intervene by EDWIN D SCHINDLER on behalf of plaintiff (mlh)
5/7/01	—	Motion(s) taken under advisement: [47-1] motion for Clarification of Page Limit Set by Local Rule 7(c) under advisement, [47-2] motion for Leave to File reply in excess of page limit under advisement, [43-1] motion to Intervene by EDWIN D SCHINDLER on behalf of plaintiff under advisement (mlh) PORTLD STNDRD
5/7/01	46	SUPPLEMENTAL FILING by EDWIN SCHINDLER in Support of His Pending Motion for Intervention (mlh) [Entry date 05/08/01]

DATE	NO.	PROCEEDINGS
5/18/01	49	OPINION of USCA re: [32-1] interlocutory appeal Decision: District Court is reversed and the temporary injunction is vacated. (Mandate Deadline set for 6/18/01) (ckb) [Entry date 05/21/01]
5/21/01	50	MOTION by EDWIN D SCHINDLER for Expedited Order on pending motion to intervene ; Response to Motion due 6/11/01 for ATTORNEY GENERAL, ME, for HS, ME COMMN (jgw)
6/8/01	51	ORDER ON EDWIN D. SCHINDLER'S MOTION TO INTERVENE denying [43-1] motion to Intervene by EDWIN D SCHINDLER on behalf of plaintiff (signed by JUDGE D. B. HORNBY) cc: cnsl (dw)
6/8/01	—	ENDORSEMENT on Motion terminating [47-1] motion for Clarification of Page Limit Set by Local Rule 7(c), granting [47-2] motion for Leave to File reply in excess of page limit (signed by JUDGE D. B. HORNBY) cc: cnsl (mmc) [Entry date 06/11/01]
6/8/01	—	ENDORSEMENT (see order issued on 6/8/01 denying motion to intervene) on Motion granting [50-1] motion for Expedited Order on pending motion to intervene (signed by JUDGE D. B. HORNBY) cc: cnsl (mmc) [Entry date 06/12/01]
6/12/01	52	MOTION by EDWIN D SCHINDLER for Reconsideration of [51-1] order denying #43 Motion to Intervene ; Response to

DATE	NO.	PROCEEDINGS
		Motion due 7/3/01 for RICHARD DONAHUE, for MAINE COUNCIL OF SEN, for MICHELLE CAMPBELL, for VIOLA QUIRION, for VIOLA QUIRION, for MAINE COUNCIL OF SEN, for ATTORNEY GENERAL, ME, for HS, ME COMMN, for PHARMACEUTICAL RESEA (err)
6/20/01	53	MEMORANDUM by EDWIN D SCHINDLER in support of [52-1] motion for Reconsideration of [51-1] order denying #43 Motion to Intervene (bld)
6/25/01	54	RESPONSE to by PHARMACEUTICAL RESEA to supplemental memo in support of [52-1] motion for Reconsideration of [51-1] order denying #43 Motion to Intervene ; Reply to Response due 7/6/01 for EDWIN D SCHINDLER (jgw) [Entry date 06/29/01]
6/29/01	55	REPLY by EDWIN D SCHINDLER to response to [52-1] motion for Reconsideration of [51-1] order denying #43 Motion to Intervene (jgw)
6/29/01	56	RESPONSE by ATTORNEY GENERAL, ME to [52-1] motion for Reconsideration of [51-1] order denying #43 Motion to Intervene ; Reply to Response due 7/10/01 for EDWIN D SCHINDLER (dw) PORTLD STNDRD

DATE	NO.	PROCEEDINGS
7/2/01	57	REPLY by EDWIN D SCHINDLER to response (#56) to [52-1] motion for Reconsideration of [51-1] order denying #43 Motion to Intervene (jgw) [Entry date 07/05/01]
7/5/01	—	Motion(s) taken under advisement: [52-1] motion for Reconsideration of [51-1] order denying #43 Motion to Intervene under advisement (jgw)
7/5/01	58	NOTICE OF INTERLOCUTORY APPEAL of [51-1] order denying mtn to intervene by EDWIN D SCHINDLER FILING FEE $ 105.00 RECEIPT # 43186 (jgw)
7/6/01	59	Amended NOTICE OF INTERLOCUTORY APPEAL of [51-1] order denying mtn to intervene by EDWIN D SCHINDLER FILING FEE $ 105.00 RECEIPT # 43190 (jgw)
7/10/01	—	ENDORSEMENT on Motion denying [52-1] motion for Reconsideration of [51-1] order denying #43 Motion to Intervene (signed by JUDGE D. B. HORNBY) cc: cnsl (jgw)
7/10/01	—	COPIES of Notice of Appeal sent to counsel. Parties: PHARMACEUTICAL RESEA, HS, ME COMMN, ATTORNEY GENERAL, ME, MAINE COUNCIL OF SEN, VIOLA QUIRION, VIOLA QUIRION, MICHELLE CAMPBELL, MAINE COUNCIL OF SEN, RICHARD DONAHUE, EDWIN D SCHINDLER (jgw)

DATE	NO.	PROCEEDINGS
7/10/01	—	CLERK'S SUPPLEMENTAL CERTIFICATE (re: [59-1] interlocutory appeal, [58-1] interlocutory appeal) ; 1ST supplemental certificate; Orig. documents numbered: 33-59 (jgw)
7/10/01	—	Transmitted supplemental record on appeal: [59-1] interlocutory appeal by EDWIN D SCHINDLER, [58-1] interlocutory appeal by EDWIN D SCHINDLER (jgw)
7/11/01	—	Deadline updated as Order issued in USCA staying entry of Mandate; reset Mandate deadline to 8/10/01 (jgw)
7/16/01	—	USCA Case Number Re: [59-1] interlocutory appeal by EDWIN D SCHINDLER, [58-1] interlocutory appeal by EDWIN D SCHINDLER USCA NUMBER: 01-2006 (jgw)
7/17/01	60	SECOND AMENDED NOTICE OF INTERLOCUTORY APPEAL of [0-0] order ENDORSEMENT on Motion denying [52-1] motion for Reconsideration of [51-1] order denying #43 Motion to Intervene, [51-1] order by EDWIN D SCHINDLER FILING FEE $ 105.00 RECEIPT # 43207 (jgw) [Edit date 07/20/01]
7/20/01	—	CLERK'S SUPPLEMENTAL CERTIFICATE (re: [60-1] interlocutory appeal) ; 2nd supplemental certificate; Orig. documents numbered: 60 (jgw)

DATE	NO.	PROCEEDINGS
7/20/01	—	Transmitted supplemental record on appeal: [60-1] interlocutory appeal by EDWIN D SCHINDLER (jgw) PORTLD STNDRD
7/20/01	—	COPIES of 2nd amended Notice of Appeal sent to counsel. Parties: PHARMACEUTICAL RESEA, HS, ME COMMN, ATTORNEY GENERAL, ME, MAINE COUNCIL OF SEN, VIOLA QUIRION, VIOLA QUIRION, MICHELLE CAMPBELL, MAINE COUNCIL OF SEN, RICHARD DONAHUE, EDWIN D SCHINDLER (jgw)
7/23/01	61	MOTION by EDWIN D SCHINDLER to Stay proceedings pending appeal of district court Order denying mtn to intervene ; Response to Motion due 8/13/01 for ATTORNEY GENERAL, ME, for HS, ME COMMN, for PHARMACEUTICAL RESEA (jgw)
8/13/01	—	Deadline updated; reset Mandate deadline to 8/17/01 (err)
8/13/01	62	RESPONSE by PHARMACEUTICAL RESEA to [61-1] motion to Stay proceedings pending appeal of district court Order denying mtn to intervene ; Reply to Response due 8/24/01 for EDWIN D SCHINDLER (err)

DATE	NO.	PROCEEDINGS
8/13/01	63	RESPONSE by HS, ME COMMN, ATTORNEY GENERAL, ME to [61-1] motion to Stay proceedings pending appeal of district court Order denying mtn to intervene ; Reply to Response due 8/24/01 for EDWIN D SCHINDLER (mmc) [Entry date 08/14/01]
8/16/01	64	REPLY by EDWIN D SCHINDLER to Dfts' response to [61-1] motion to Stay proceedings pending appeal of district court Order denying mtn to intervene (jgw)
8/16/01	65	REPLY by EDWIN D SCHINDLER to pltf's response to [61-1] motion to Stay proceedings pending appeal of district court Order denying mtn to intervene (jgw)
8/16/01	—	Motion(s) taken under advisement: [61-1] motion to Stay proceedings pending appeal of district court Order denying mtn to intervene under advisement (jgw)
8/20/01	66	(NOTICE) MEMORANDUM by EDWIN D SCHINDLER in support of [61-1] motion to Stay proceedings pending appeal of district court Order denying mtn to intervene (jgw)
8/20/01	—	ENDORSEMENT on Motion denying [61-1] motion to Stay proceedings pending appeal of district court Order denying mtn to intervene "Denied. (There are no proceedings currently pending before this court.)" (signed by JUDGE D. B. HORNBY) cc: cnsl (mnm) [Entry date 08/21/01]

DATE	NO.	PROCEEDINGS
8/24/01	67	NOTICE OF INTERLOCUTORY APPEAL to the Federal Circuit Court of Appeals of [0-0] order ENDORSEMENT on Motion denying [52-1] motion for Reconsideration of [51-1] order denying #43 Motion to Intervene, [51-1] order by EDWIN D SCHINDLER FILING FEE $ 105.00 RECEIPT # 43249 (jgw) PORTLD STNDRD
8/24/01	—	COPIES of Notice of Appeal sent to counsel. Parties: PHARMACEUTICAL RESEA, HS, ME COMMN, ATTORNEY GENERAL, ME, MAINE COUNCIL OF SEN, VIOLA QUIRION, VIOLA QUIRION, MICHELLE CAMPBELL, MAINE COUNCIL OF SEN, RICHARD DONAHUE, EDWIN D SCHINDLER (jgw)
8/29/01	68	ORDER from U.S. Court of Appeals rescinding Order dated August 13, 2001 issuing mandate (jgw)
8/29/01	69	ORDER from U.S. Court of Appeals denying motion to stay mandate by amicus curiae Edwin R. [sic] Schindler (jgw)
9/4/01	—	U.S. COURT OF APPEALS FOR THE FEDERAL CIRCUIT; Case Number Re: [67-1] interlocutory appeal by EDWIN D SCHINDLER USCA NUMBER: 01-1597 (jgw)
9/4/01	—	Deadline updated; reset Mandate deadline to 9/11/01 (err)

DATE	NO.	PROCEEDINGS
9/13/01	—	Deadline updated; reset Mandate deadline to 9/17/01 (bld)
9/18/01	—	Deadline updated; reset Mandate deadline to 10/1/01 (jgw)
9/19/01	70	MANDATE/JUDGMENT OF USCA (certified copy) dated 8/13/01 Re: [32-1] interlocutory appeal by ATTORNEY GENERAL, ME, HS, ME COMMN Decision: Judgment of USDC reversed and temporary injunction vacated (please refer to USCA Order #68 rescinding issuance of this mandate) (jgw) [Entry date 09/21/01]
10/9/01	71	MOTION by EDWIN D SCHINDLER to Intervene by EDWIN D SCHINDLER to appeal anticipated entry of final judgment against PhRMA ; Response to Motion due 10/30/01 for ATTORNEY GENERAL, ME, for HS, ME COMMN, for PHARMACEUTICAL RESEA (jgw) [Entry date 10/10/01] [Edit date 10/10/01]
10/9/01	72	MOTION by EDWIN D SCHINDLER to Stay proceedings in USDC pending appeal in Federal Circuit ; Response to Motion due 10/30/01 for ATTORNEY GENERAL, ME, for HS, ME COMMN, for PHARMACEUTICAL RESEA (jgw) [Entry date 10/10/01]

DATE	NO.	PROCEEDINGS
10/10/01	73	WITHDRAWAL of [71-1] motion to Intervene by EDWIN D SCHINDLER to appeal anticipated entry of final judgment against PhRMA, [72-1] motion to Stay proceedings in USDC pending appeal in Federal Circuit (jgw)
10/22/01	74	MANDATE/JUDGMENT OF Federal Circuit Court (certified copy) Re: [67-1] interlocutory appeal by EDWIN D SCHINDLER Decision: Maine dfts mtn to dismiss this appeal granted; Schindler's motions are moot; Schindler's petition for writ of mandamus is denied (jgw) [Edit date 10/22/01] PORTLD STNDRD
10/30/01	75	Interlocutory MANDATE/JUDGMENT OF USCA (certified copy) Re: [60-1] interlocutory appeal by EDWIN D SCHINDLER, [59-1] interlocutory appeal by EDWIN D SCHINDLER, [58-1] interlocutory appeal by EDWIN D SCHINDLER Decision: Appeal DISMISSED (err) [Entry date 10/31/01] [Edit date 10/31/01]
5/28/02	76	MOTION by PHARMACEUTICAL RESEA for Allen S. Rugg to Withdraw as Counsel (err)
5/29/02	—	ENDORSEMENT on Motion granting [76-1] motion for Allen S. Rugg to Withdraw as Counsel ("Granted. Other counsel have appeared.") (signed by MAG. JUDGE MARGARET J. KRAVCHUK) cc: cnsl (err)

UNITED STATES COURT OF APPEALS
FOR THE FIFTH CIRCUIT

No. 00-2446

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA,
Plaintiff-Appellee,

v.

COMMISSIONER, MAINE DEPARTMENT OF HUMAN SERVICES; ATTORNEY GENERAL, ME
Defendants-Appellants.

DOCKET ENTRIES

DATE	PROCEEDINGS
11/22/00	CIVIL CASE docketed. Opening forms sent. Notice filed by Appellants Commissioner, and Attorney General, ME. Appearance form due 12/6/00. Docketing Statement due 12/6/00. [00-2446] (cmpa) [00-2446]
11/22/00	RECORD filed: 1 volume(s). Transcript of Hearing on Preliminary Injunction included. [516840-1] [00-2446] (cmpa) [00-2446]
11/29/00	TRANSCRIPT REPORT/ORDER filed by Appellants Commissioner and Attorney General, ME. Transcript is already on file in the Clerk's office. [00-2446] (cmpa) [00-2446]
11/29/00	BRIEFING SCHEDULE. Appellant's Brief due 1/8/01. Appendix due 1/8/01. Appellee's Brief due 2/7/01. Reply brief due 2/21/01. [00-2446] (cmpa) [00-2446]

DATE	PROCEEDINGS
11/30/00	MOTION filed by Appellant Commissioner of the Maine Department of Human Services and Attorney General, ME to expedite appeal. Certificate of service 11/28/00. [00-2446] (cmpa) [00-2446]
11/30/00	APPEARANCE filed by Kathleen M. Sullivan for Appellees Pharmaceutical Research Pharmaceutical and Manufacturers of America. [518686-1] [00-2446] (cmpa) [00-2446]
11/30/00	APPEARANCE filed by Andrew S. Hagler for Appellants Attorney General, ME, and Commissioner. [519912-1] [00-2446] (cmpa) [00-2446]
11/30/00	DOCKETING STATEMENT filed by Appellants Commissioner and Attorney General, ME. [00-2446] (cmpa) [00-2446]
12/4/00	DISCLOSURE STATEMENT on behalf of Appellee Pharmaceutical Resea filed. [00-2446] (cmpa) [00-2446]
12/4/00	APPEARANCE filed by Bruce C. Gerrity for Appellee Pharmaceutical Research. [519891-1] [00-2446] (cmpa) [00-2446]
12/4/00	APPEARANCE filed by Allen S. Rugg for Appellee Pharmaceutical Research. [519894-1] [00-2446] (cmpa) [00-2446]
12/4/00	APPEARANCE filed by John R. Brautigam for Appellants Attorney General, ME, and Commissioner. [519896-1] [00-2446] (cmpa) [00-2446]

DATE	PROCEEDINGS
12/5/00	RESPONSE filed by Appellee Pharmaceutical Research to motion to expedite appeal [518606-1]. Parties agree on briefing schedule. Certificate of service dated 12/5/00 [519953-1] [00-2446] (cmpa) [00-2446]
12/5/00	APPEARANCE filed by Daniel M. Price for Appellee Pharmaceutical Research. [519957-1] [00-2446] (cmpa) [00-2446]
12/11/00	ORDER filed. Appellants' motion for an expedited appeal is granted to the extent set out in the parties' agreed upon briefing schedule. That is, appellants' brief will be due by January 8, 2001, appellee's brief shall be filed within thirty days of the date of the filing of appellants' brief, and appellants' reply brief will be due within fourteen days of the filing of appellee's brief. If the briefs are filed according to this schedule, then oral argument will be scheduled for the court's March 2001 sitting. (ciny) [00-2446]
12/11/00	BRIEFING SCHEDULE. Appellant's Brief due 1/8/01. Appendix due 1/8/01. Appellee's Brief due 2/7/01. Reply brief due 2/21/01. [00-2446] (ciny) [00-2446]
12/11/00	LETTER filed by Thomas C. Bradley on behalf of the Maine Citizen Leadership Fund informing the court that a motion to intervene was filed on their behalf in the district court. [00-2446] (kati) [00-2446]

DATE	PROCEEDINGS
1/9/01	BRIEF filed by Appellant Attorney General, ME and Appellant Kevin Concannon. Pages: 60. Copies: 10, delivered by mail. Certificate of service date 01/08/01. [526780-1] Appellee brief due 2/8/01. [00-2446] (karn) [00-2446]
1/9/01	ELECTRONIC DOCUMENT filed by Appellant Commissioner and Appellant Attorney General, ME. [00-2446] (karn) [00-2446]
1/9/01	APPENDIX filed by Appellant Commissioner and Appellant Attorney General, ME. Copies: 5. Volumes: 1. Delivered by mail, filed. Certificate of service date 1/8/01. [526805-1] [00-2446] (karn) [00-2446]
1/17/01	APPEARANCE filed by Thomas Charles Bradley for Amicus Curiae Richard Donahue, Amicus Curiae Michelle Campbell. [529329-1] [00-2446] (mlyn) [00-2446]
1/17/01	APPEARANCE filed by Arn H. Pearson for Amicus Curiae Richard Donahue, Amicus Curiae Michelle Campbell, Amicus Curiae Viola Quirion, Amicus Curiae Maine Council. [529333-1] [00-2446] (mlyn) [00-2446]
1/17/01	MOTION filed by Amicus Curiae Maine Council, Amicus Curiae Viola Quirion, Amicus Curiae Michelle Campbell, Amicus Curiae Richard Donahue to file appendix. Certificate of service dated 1/16/01. [00-2446] (mlyn) [00-2446]
1/18/01	PARTY Amicus Curiae Michelle Campbell, Amicus Curiae Richard Donahue added to case. [00-2446] (mlyn) [00-2446]

DATE	PROCEEDINGS
1/18/01	ORDER filed granting motion of the Amicus parties to file an appendix. [00-2446] (mlyn) [00-2446]
1/18/01	BRIEF filed by Amicus Curiae Maine Council, Amicus Curiae Viola Quirion, Amicus Curiae Michelle Campbell, Amicus Curiae Richard Donahue in support of appellants. Pages: 29, Copies: 9, delivered by mail. Certificate of service date 1/16/01. [529342-1] [00-2446] (mlyn) [00-2446]
1/18/01	APPENDIX filed by Amicus Curiae Maine Council, Amicus Curiae Viola Quirion, Amicus Curiae Michelle Campbell, Amicus Curiae Richard Donahue. Copies: 5. Volumes: 1. Delivered by mail, filed. Certificate of service date 1/16/01. [529343-1] [00-2446] (mlyn) [00-2446]
1/22/01	ELECTRONIC DOCUMENT filed by Amicus Curiae Maine Council, Amicus Curiae Viola Quirion, Amicus Curiae Michelle Campbell, Amicus Curiae Richard Donahue. To replace original disk sent with Amicus brief. Original was in MS Word. [00-2446] (cmpa) [00-2446]
1/24/01	Assigned for the month of March, (3/5/01). [00-2446] (ceca) [00-2446]
2/1/01	ATTORNEY Marinn F. Carlson for Appellee Pharmaceutical Research added to case. [00-2446] (cmpa) [00-2446]
2/1/01	APPEARANCE filed by Marinn F. Carlson for Appellee Pharmaceutical Resea. [534128-1] [00-2446] (cmpa) [00-2446]

DATE	PROCEEDINGS
2/8/01	BRIEF filed by Appellee Pharmaceutical Research. Pages: 40, Copies: 10, delivered by mail. Certificate of service date 2/7/01. [534738-1] Reply brief due 2/22/01. [00-2446] (cmpa) [00-2446]
2/9/01	PARTY Abbott Laboratories, AMGEN, Inc., Bristol-Myers, Glaxo Wellcome PLC, Smithkline Beecham, Johnson & Johnson, Merck Company, Pfizer, Inc., Procter & Gamble Co., Schering Corp added to case. These companies are part of Pharmaceutical Research and Manufacturers of America. [00-2446] (tim) [00-2446]
2/12/01	MOTION filed Edwin D. Schindler. "Motion for Leave to File Amicus Curiae Brief in Support of Plaintiff-Appellee Seeking Affirmance, and for Participation in Oral Argument, Pursuant to Fed.R.App.P. 29(b) and (g)" Certificate of service dated 2/10/01. [00-2446] (cmpa) [00-2446]
2/14/01	RESPONSE faxed and filed by Appellee Pharmaceutical Research. "Response to Amicus Curiae Schindler's Motion for Leave to Participate in Oral Argument" [535686-1]. Certificate of service dated 2/14/01 [536689-1] [00-2446] (cmpa) [00-2446]
2/15/01	BRIEF filed by Amicus Curiae Chamber of Commerce of the United States in support of Appellee Pharmaceutical Research and Manufacturer of America. Pages: 19, Copies: 9, delivered by mail. Certificate of service date 2/14/01. [536917-1] [00-2446] (cmpa) [00-2446]

DATE	PROCEEDINGS
2/15/01	PARTY Added. Amicus Curiae Chamber of Commerce added to case. [00-2446] (cmpa) [00-2446]
2/15/01	DISCLOSURE STATEMENT on behalf of Amicus Curiae Chamber of Commerce of the United States filed. [00-2446] (cmpa) [00-2446]
2/16/01	ELECTRONIC DOCUMENT filed by Amicus Curiae Chamber of Commerce. Disk of Amicus brief. [00-2446] (cmpa) [00-2446]
2/16/01	RESPONSE filed by Appellant Commissioner, Maine Department of Human Services and Attorney General, ME. "Memorandum in Opposition to Motion of Edwin D. Schindler for Leave to File an Amicus Curiae Brief" Certificate of service dated 2/15/01 [537228-1] [00-2446] (cmpa) [00-2446]
2/16/01	PARTY ADDED. Amicus Curiae Washington Legal, Amicus Curiae Allied Educational, Amicus Curiae International Patien, Amicus Curiae Kidney Cancer Assoc., Amicus Curiae Seniors Coalition, Amicus Curiae 60 Plus Assoc. added to case. [00-2446] (cmpa) [00-2446]
2/16/01	DISCLOSURE STATEMENT on behalf of Amicus Curiae Washington Legal, Amicus Curiae Allied Educational, Amicus Curiae International Patien, Amicus Curiae Kidney Cancer Assoc., Amicus Curiae Seniors Coalition, and Amicus Curiae 60 Plus Assoc. filed. [00-2446] (cmpa) [00-2446]

DATE	PROCEEDINGS
2/16/01	ELECTRONIC DOCUMENT filed by Amicus Curiae Washington Legal, Amicus Curiae Allied Educational, Amicus Curiae International Patien, Amicus Curiae Kidney Cancer Assoc., Amicus Curiae Seniors Coalition, Amicus Curiae 60 Plus Assoc. Disk to Amicus Curiae Brief. [00-2446] (cmpa) [00-2446]
2/16/01	BRIEF filed by Amicus Curiae Washington Legal, Amicus Curiae Allied Educational, Amicus Curiae International Patien, Amicus Curiae Kidney Cancer Assoc., Amicus Curiae Seniors Coalition, Amicus Curiae 60 Plus Assoc. in support of Appellee Pharaceutical Research. Copies: 10, delivered by mail. Certificate of service date 2/14/01. [538082-1] [00-2446] (cmpa) [00-2446]
2/20/01	RESPONSE filed by Edwin D. Schindler. "Reply Memorandum of Amicus Curiae Edwin Schindler on Motion for Leave to File Amicus Brief" Certificate of service dated 2/19/01 [537538-1] [00-2446] (cmpa) [00-2446]
2/21/01	APPEARANCE filed by Richard A. Samp and Daniel J. Popeo for Amicus Curiae 60 Plus Assoc., Amicus Curiae Seniors Coalition, Amicus Curiae Kidney Assoc., Amicus Curiae International Patien, Amicus Curiae Allied Educational, Amicus Curiae Washington Legal. [538154-1] [00-2446] (cmpa) [00-2446]
2/22/01	APPEARANCE filed by Steven J. Rosenbaum for Amicus Curiae Chamber of Commerce. [538348-1] [00-2446] (karn) [00-2446]

DATE	PROCEEDINGS
2/22/01	ELECTRONIC DOCUMENT (brief on disk) filed by Appellants Commissioner and Attorney General, ME. [00-2446] (frnk) [00-2446]
2/23/01	ORDER filed. Upon consideration of "Motion For Leave To File Amicus Curiae Brief In Support Of Plaintiff-Appellee Seeking Affirmance, And For Participation In Oral Argument, Pursuant To Fed. R. App. P. 29(b) and (g)," It is ordered that the motion to file an Amicus Brief is hereby granted. The request to participate in oral argument is denied. [00-2446] (bety) [00-2446]
2/23/01	PARTY Amicus Curiae Edwin D. Schindler added to case. [00-2446] (bety) [00-2446]
2/23/01	Brief of Amicus Curiae Edwin D. Schindler in support of plaintiff-appellee seeking affirmance. Pages: 36, (5,969 words) Copies: 10, delivered by mail. Certificate of service date 2/12/01. [538836-1] [00-2446] (bety) [00-2446]
2/23/01	REPLY BRIEF filed by Appellant's Commissioner and Attorney General, ME. Pages: 29, Copies: 10, delivered mail. Certificate of service date 2/22/01. [538878-1] [00-2446] (frnk) [00-2446]
2/27/01	APPEARANCE filed by Steven J. Rosenbaum for Amicus Curiae Chamber of Commerce of the United States. [539456-1] [00-2446] (cmpa) [00-2446]
2/27/01	APPEARANCE filed for Amicus Curiae Edwin D. Schindler, pro se. [541125-1] [00-2446] (cmpa) [00-2446]

DATE	PROCEEDINGS
3/5/01	CASE ARGUED 03/05/01. Bownes, Keeton, Saris, JJ. (ceca) [00-2446]
5/16/01	OPINION filed. Senior Circuit Judge Bownes, District Court Judge Keeton, and District Court Judge Saris. Signed Judge Hugh H. Bownes, aut PUBLISHED. [563283-1] [00-2446] (cmpa) [00-2446]
5/16/01	JUDGMENT entered by Senior Circuit Judge Bownes, District Court Judge Keeton, and District Court Judge Saris closing case. The Judgment of the district court is reversed and the temporary injunction is vacated. [563284-1] [00-2446] (cmpa) [00-2446]
5/30/01	PETITION filed by Appellee Pharmaceutical Reseach and Manufacturers of America's for rehearing en banc. [567137-1] [00-2446] Certificate of Service dated 5/29/01. [00-2446] (mlyn) [00-2446]
6/7/01	LETTER filed by Computer Research Services. Research firm writes, "Please forward copies of the following documents..." [00-2446] (cmpa) [00-2446]
6/12/01	SUPPLEMENTAL AUTHORITY pursuant to FRAP 28j filed by Appellee Pharmaceutical Research. Certificate of Service 6/11/01 [00-2446] (cmpa) [00-2446]

DATE	PROCEEDINGS
6/13/01	ORDER. Senior Circuit Judge Hugh H. Bownes, District Court Judge Robert E. Keeton, District Court Judge Patti B. Saris. The panel that heard this case has voted to deny the petition for panel rehearing. For the following reasons, there can be no action taken on the petition for rehearing en banc. None of the members of the panel are eligible to vote on the petition for rehearing en banc. Federal Rule of Appellate Procedure 35(a) provides in pertinent part: When Hearing or Rehearing En Banc May Be Ordered. A majority of the circuit judges who are in regular active service may order that an appeal or other proceeding be heard or reheard by the court of appeals en banc. See United States v. Leichter, 167 F.3d 667 (1st Cir. 1999) (absolute majority of active judges is needed to grant rehearing en banc). -2- Judges Keeton and Saris are United States District Court Judges and Judge Bownes is a Senior Circuit Court Judge. All of the active Circuit Court Judges with the exception of Chief Judge Torruella have recused themselves from this case. The petition for rehearing en banc must, therefore, be denied. Chief Judge Torruella wants to be recorded as voting "in favor of rehearing en banc, based on the opinion of the District Court." Judgment shall issue in accord with the Rules. [00-2446] (cmpa) [00-2446]
6/19/01	MOTION filed by Appellee Pharmaceutical Research. "Plaintiff-Appelee's Motion to Stay the Mandate Pending Filing of a Petition for Writ of Certiorari." [572393-1] Certificate of service dated 6/19/01. [00-2446] (cmpa) [00-2446]

DATE	PROCEEDINGS
6/29/01	Defendants-appellants' opposition to plaintiff-appellee's motion to stay the mandate [572393-1]. Certificate of service dated 6/28/01 [574576-1] [00-2446] (bety) [00-2446]
7/3/01	ORDER filed by Senior Circuit Judge Hugh H. Bownes, District Court Judge, and District Court Judge Robert E. Keeton. Mandate is stayed for 28 days to July 31, 2001. (cmpa) [00-2446]
7/13/01	RECORD filed: 2 vol(s). Documents 33-59. Filed in lead case 00-2446. [577814-1] [01-2006, 00-2446] (cmpa) [00-2446 01-2006]
7/17/01	MOTION filed by Appellant Edwin D. Schindler. "Motion to Dismiss for Lack of Appellate Jurisdiction or, in the Alternative, for Transfer to the United States Court of Appeals for the Federal Circuit" Certificate of Service dated 07/16/01. (cmpa) [00-2446]
7/25/01	MOTION filed by Amicus Curiae Edwin D. Schindler. "Motion to Stay Mandate Pending Determination on Pending Motion to Dismiss for Lack of Appellate Jurisdiction..." to further stay mandate until 7/24/01 Certificate of service dated 7/24/01 . [00-2446] (cmpa) [00-2446]
7/30/01	RESPONSE filed by Attorney General, ME. LETTER filed by State of Maine. The Attorney General's Office responds to the motions Edwin Schindler has filed in 00-2446 and 01-2006. Certificate of service dated 7/27/01 [581972-1] [00-2446, 01-2006] (cmpa) [00-2446 01-2006]

DATE	PROCEEDINGS
7/30/01	REPLY filed by Amicus Curiae Edwin D. Schindler. "Reply to Maine's Letter of July 27, 2001 on the Pending Motion to Dismiss for Lack of Appellate Jurisdiction or, in the Alternative, for Transfer to the United States Court of Appeals for the Federal Circuit" Certificate of service dated 7/28/01 [581982-1] [00-2446] (cmpa) [00-2446]
7/31/01	LETTER filed by Daniel M. Price. Appellee PhRMA has filed a Petition for a Writ of Certiorari at the United States Supreme Court. Counsel writes that "PhRMA's filing today in Washington D.C. automatically extends that stay until the Supreme Court disposes of the petition." [00-2446] (cmpa) [00-2446]
8/3/01	U.S. SUPREME COURT NOTICE filed regarding petition for writ of certiorari. Filed in the Supreme Court on [583793-1] 08/01/01. Supreme Court case number: 01-188. [00-2446] (cmpa) [00-2446]
8/13/01	ORDER filed by Chief Judge Hugh H. Bownes. Upon consideration of "Motion to Dismiss for Lack of Appellate Jurisdiction or, in the Alternative, for Transfer to the United States Court of Appeals the Federal Circuit" and response, It is hereby ordered that said motion is denied. (cmpa) [00-2446]
8/13/01	ORDER filed by Chief Judge Hugh H. Bownes. Upon consideration of the motion to further stay mandate and response, it is ordered that said motion be denied. (cmpa) [00-2446]

DATE	PROCEEDINGS
8/13/01	MANDATE ISSUED. [00-2446] (cmpa) [00-2446]
8/13/01	RECORD retained for companion case number(s): 01-2006. Record remains filed under 00-2446. [00-2446] (cmpa) [00-2446]
8/21/01	MOTION filed by Appellee Pharmaceutical Resea in 00-2446 to recall mandate. Certificate of service dated 8/20/01. [00-2446] (cmpa) [00-2446]
8/27/01	ORDER filed by Senior Circuit Judge Hugh H. Bownes. The Order of August 13, 2001 issuing the mandate is hereby rescinded. (cmpa) [00-2446]
8/27/01	ORDER filed by Senior Circuit Judge Hugh H. Bownes. The Motion to Stay Mandate filed by Amicus Curiae Edwin R. [sic] Schindler is hereby denied. (cmpa) [00-2446]
5/13/02	PUBLIC NOTE: "Notice of Change of Address" Daniel M. Price and Marinn F. Carlson have moved their practices to the law firm of Sidley Austin Brown & Wood LLP in Washington, D.C. their new address is: Sidley Austin Brown & Wood LLP, 1501 K Street NW, Washington, D.C. 20005. Tel: 202-736-8000 Fax: 202-736-8711. [00-2446] (cmpa) [00-2446]
5/20/02	ATTORNEY MOTION filed by Allen S. Rugg for Appellee Pharmaceutical Research. "Motion for Leave to Withdraw" Certificate of service dated 5/17/02. [00-2446] (cmpa) [00-2446]

DATE	PROCEEDINGS
5/22/02	ORDER. Leave is hereby granted Attorney Allen S. Rugg to withdraw as counsel for the appeilee, Pharmaceutical Research & Manufacturers of America. (cmpa) [00-2446]
7/5/02	U.S. SUPREME COURT ORDER granting petition for writ of certiorari filed in the Supreme Court on 06/28/02. (cmpa) [00-2446]
7/15/02	RECORD returned to originating court. Debbie Whitney at the district court has requested that this record be sent back. The mandate has not issued. ** Documents 1-60; Hearing on Preliminary Injunction held on 10/19/00 ** (cmpa) [00-2446]

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MAINE

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA
1100 Fifteenth Street, N.W.
Washington, DC 20005

Plaintiff,

v.

KEVIN CONCANNON, in his official capacity as Commissioner of the Department of Human Services for the State of Maine
221 State Street
Augusta, Maine 04333

ANDREW KETTERER, in his official capacity as Attorney General for the State of Maine
6 State House Station
Augusta, Maine 04333

Defendants.

Civil Action No. _____

COMPLAINT FOR DECLARATORY, INJUNCTIVE AND OTHER RELIEF

Plaintiff, Pharmaceutical Research and Manufacturers of America ("PhRMA"), by its undersigned attorneys, states in support of this Complaint as follows:

INTRODUCTION

1. This is an action for declaratory, injunctive and other relief brought by PhRMA against Defendant Kevin Concannon, the Commissioner of the Department of Health and Human Services of the State of Maine, in his official capacity, and against Defendant Andrew Ketterer, Attorney General of the State of Maine, in his official capacity. Plaintiff seeks injunctive and declaratory relief barring the implementation and enforcement of specified provisions of the Act to Establish Fairer Pricing for Prescription Drugs, 2000 Me. Legis. Ch. 786 (S.P. 1026) (L.D. 2599) (West) (hereinafter the "Act," provisions hereinafter cited to Section ____ of 22 M.R.S.A., copy attached as Exhibit A hereto), and declaring them unlawful.

2. The challenged provisions of the Act (1) require drug manufacturers to finance drug discounts to Maine residents, and threaten to restrict Maine Medicaid beneficiaries' access to the manufacturers' drugs; (2) punish drug manufacturers for charging prices and realizing profits that the State deems to be excessive, even in out-of-state transactions; and (3) punish drug manufacturers for rearranging their affairs so as to minimize their exposure to these provisions of the Act while continuing to ensure that their drugs will be available to Maine residents.

3. The challenged provisions of the Act violate the Commerce Clause of the United States Constitution by regulating transactions that occur outside Maine, by tying the discounts that drug manufacturers must provide for drugs dispensed in Maine to price discounts provided in other jurisdictions, and by preventing drug manufacturers from modifying their channels of distribution in response to the Act.

4. The challenged provisions of the Act also violate the Supremacy Clause of the United States Constitution by imposing restrictions on patients' access to manufacturers'

drugs in the federal Medicaid program to punish manufacturers who do not participate in the new Maine drug program.

PARTIES

5. Plaintiff, PhRMA, is a non-profit corporation, organized and existing under the laws of the State of Delaware.

6. PhRMA represents the country's leading research-based pharmaceutical and biotechnology companies, which are devoted to inventing medicines that allow patients to lead longer, healthier, and more productive lives. PhRMA's member companies account for more than 75 percent of brand name drug sales in the United States.

7. PhRMA serves as the pharmaceutical industry's principal policy advocate, representing its members' interests in matters before Congress, the Executive Branch, state regulatory agencies and legislatures, and the courts. PhRMA is committed to, *inter alia*, advancing public policies that foster continued innovation, educating the public about the drug development and discovery process, and promoting a fair and competitive marketplace. PhRMA has represented its members in connection with the Maine Legislature's consideration of legislation regulating prescription drugs, including the legislation ultimately enacted as the Act challenged here.

8. All of PhRMA's members have their principal places of business outside Maine. By far the greatest part of PhRMA's members' prescription drug sales are to wholesalers and other entities located outside Maine. With limited exceptions, PhRMA's members are not parties to sales transactions occurring in, or with purchasers in or from, the state of Maine.

9. PhRMA brings this suit on behalf of its members. At least one of PhRMA's members possesses standing to sue in

its own right; the regulation of prescription drug pricing is of vital concern to PhRMA's members; and neither the claim asserted nor the relief demanded necessitates the participation of individual PhRMA members.

10. Defendant Kevin Concannon is the Commissioner of the Department of Human Services (hereinafter the "Department") for the State of Maine. Defendant Concannon is sued in his official capacity only.

11. Pursuant to the Act, Defendant Concannon (hereinafter, the "Commissioner") is responsible, directly and through his Department, for the implementation and, in substantial part, enforcement of the Act.

12. Defendant Andrew Ketterer is the Attorney General of the State of Maine. Defendant Ketterer is sued in his official capacity only.

13. Pursuant to the Act, Defendant Ketterer (hereinafter, the "Attorney General") is responsible for the enforcement of the profiteering provisions of the Act.

JURISDICTION

14. Subject matter jurisdiction is founded on 28 U.S.C. §§ 1331 and 1343 because this case arises under the Constitution and laws of the United States.

15. This Court has authority to grant declaratory relief pursuant to 28 U.S.C. §§ 2201 and 2202.

VENUE

16. Venue is proper in this Court under 28 U.S.C. § 1391(b) because the Defendants maintain their offices within this judicial district and because the events giving rise to the claims herein occurred within this judicial district.

THE MAINE Rx LAW

17. The Act, which was not accorded the regular public hearing and public work session processes of the Maine Legislature, enacts a new Chapter 603, entitled "Prescription Drug Access," in Maine Rev. Stat. Ann. Title 22.

18. Chapter 603 includes among its principal components (1) a mandatory prescription drug "rebate" program, and (2) penalties for "profiteering" in prescription drugs (including penalties for taking actions to minimize exposure to the Act).

The Maine Rx Program

19. Subchapter I (§ 2681) of the new Chapter 603 establishes the "Maine Rx Program," a prescription drug rebate program administered by the State (specifically, by the Department) for "qualified" Maine residents.

20. As administered by the Department, the class of "qualified" Maine residents will include the 325,000 Maine residents who do not have prescription drug coverage under other public or private programs.

21. Under the new Maine Rx Program, drug manufacturers are required to remit payments to Maine called "rebates." Maine in turn is required to use these payments to finance discounts provided by retail pharmacies to enrollees in the Maine Rx Program. The Act, through the "rebate" mechanism, thereby effectively transfers to Maine residents a portion of the purchase price received by the manufacturers from their customers (typically wholesalers and distributors). As the Program is being administered by the Department, manufacturers are required to remit these payments regardless of whether their sales occurred outside Maine.

22. In particular, Section 2681(3) requires all prescription drug manufacturers and labelers whose drugs are sold in Maine through publicly supported pharmaceutical assistance programs, such as the federal Medicaid program, to enter into

agreements with the Department to provide such "rebates" for their prescription drugs that are dispensed to Maine residents under the Maine Rx Program.

23. PhRMA members participate in Medicaid.

24. PHRMA members also participate in Maine's Elderly Low-Cost Drug Program (hereinafter the "Elderly LCD Program"), a publicly supported pharmaceutical assistance program.

25. The PhRMA members who participate in these publicly supported pharmaceutical assistance program in Maine are thus required by Section 2681(3) to enter into rebate agreements for the Maine Rx Program.

26. The Act directs the Commissioner to negotiate the amount of the rebate required from each manufacturer under the obligatory rebate agreement.

27. The Act directs the Commissioner to use his "best efforts" to obtain an initial rebate for the Maine Rx Program equal to or greater than the manufacturer's nationwide, statutorily-specified federal Medicaid rebate. Such initial rebates are to take effect beginning January 1, 2001.

28. On August 2, 2000 the Commissioner presented pharmaceutical manufacturers with a "Rebate Agreement," for signature no later than November 1, 2000, that requires payment of "the Medicaid Rebate amount" on drugs dispensed under the Maine Rx program.

29. The Act also directs the Commissioner to negotiate for further rebates, to take effect no later than October 1, 2001, that are equal to or greater than any discount, rebate or price the manufacturer gives in connection with any federal program.

30. If a manufacturer does not enter into a Maine Rx rebate agreement, the Department is directed by Sections 2681(7) and 3174-Y to impose a "prior authorization" requirement on

the manufacturer's drugs that are dispensed—not under the Maine Rx program—but under the entirely distinct federal Medicaid drug program.

31. Prior authorization is intended to limit access to a drug. It does so by requiring a physician who wishes to prescribe the drug to Medicaid patients to justify his or her reasons for doing so to the state Medicaid Administrator on a case-by-case basis in order to obtain specific prior permission from the Administrator. Absent such authorization, the Medicaid patient will not receive coverage for the prescription.

32. The Act's rebate requirement is conjoined with prohibitions on "profiteering" (discussed *infra* at paragraphs 38-46) that, *inter alia*, prevent manufacturers from rearranging their affairs to minimize their exposure to the rebate requirement while continuing to make their drugs available to Maine residents.

33. With the exception of an initial loan from the Trust Fund for a Healthy Maine in fiscal year 2000-01, which must be repaid in fiscal year 2002-03 using rebate revenues collected from manufacturers, the Maine Rx program is to be funded exclusively by the manufacturers' rebate payments through the establishment of the "Maine Dedicated Fund."

34. Maine Rx is thus a pass-through program, under which the State itself does not purchase prescription drugs or contribute state funds to subsidize prescription drug purchases by residents covered by the Maine Rx Program.

35. In addition to establishing the new Maine Rx Program, the Act (Section 254 ss. 8-A) revises the State's existing, voluntary Elderly LCD Program to make participation mandatory for all manufacturers who participate in Medicaid.

36. The Elderly LCD Program receives state funding support.

37. Under the Maine Elderly LCD Program, manufacturers give the State rebates equivalent to those calculated under Medicaid.

Anti-Profiteering

38. Section 2697 declares unlawful the act of "profiteering" in prescription drugs.

39. Manufacturers, labelers, and distributors of prescription drugs are deemed to engage in "illegal profiteering" if they: (1) exact or demand an "unconscionable" price; (2) exact or demand prices or terms that lead to an "unjust or unreasonable" profit; (3) "discriminate[] unreasonably" in selling or distributing drugs dispensed in Maine; or (4) intentionally restrict the sale or distribution of drugs in Maine in retaliation for the Act.

40. The Act's anti-profiteering prohibitions relating to prices, profits, and preferential terms, Sections 2697(A)-(C), are not by their terms confined to transactions occurring in Maine.

41. The Act's fourth anti-profiteering provision, Section 2697(D), precludes manufacturers from rearranging their affairs so as to minimize exposure to the rebate requirement and the anti-profiteering provisions.

42. Violations of the anti-profiteering provisions are punishable by, *inter alia*, injunctive relief, treble damages, punitive damages, and civil penalties of up to $100,000 per violation, plus costs and attorney's fees.

43. Violations of the anti-profiteering provisions of the Maine Rx Law are also deemed to violate the Maine Unfair Trade Practices Act.

44. Violations of the Maine Unfair Trade Practices Act are punishable by, *inter alia*, injunctive relief, damages, restitution, and civil penalties of up to $10,000 per violation.

45. The Attorney General is responsible for investigating suspected violations of the Act's anti-profiteering provisions and the Maine Unfair Trade Practices Act, and for prosecuting civil violations thereof.

46. Violations of the Maine Unfair Trade Practices Act are also subject to private actions for damages, restitution, and equitable relief. Successful plaintiffs may also recover attorney's fees and costs.

THE FEDERAL MEDICAID PROGRAM

47. Medicaid is a federally mandated, state-administered program that operates under federal guidelines to provide medical care to certain low-income populations. The program is jointly funded by the federal and state governments.

48. In 1991 Congress supplemented the federal Medicaid health care program with a rebate program to offset the costs of prescription drug coverage, which states may opt to offer to Medicaid beneficiaries. Omnibus Budget Reconciliation Act ("OBRA") of 1990, enacting § 1927 of the Social Security Act, 42 U.S.C. § 1396r-8.

49. Under the Medicaid drug program, drug manufacturers enter into national rebate agreements with the Secretary of the Department of Health and Human Services. 42 U.S.C. § 1396r-8(a)(1). Pursuant to those agreements, manufacturers pay statutorily-calculated rebates directly to each state for their drugs dispensed to Medicaid beneficiaries in the state. 42 U.S.C. § 1396r-8(b), (c); 56 Fed. Reg. 7049 (1991). The states also receive federal Medicaid reimbursement funds for those drugs, and contribute state funds to make up the balance (such that the Medicaid beneficiary makes no more than a nominal payment).

50. For each drug, a manufacturer pays the same nationwide Medicaid rebate. 42 U.S.C. § 1396r-8(c)(1)(A).

51. The formula for calculation of that rebate is prescribed by statute. 42 U.S.C. § 1396r-8(c)(1).

52. The calculation of the rebate starts with the per-unit Average Manufacturer Price ("AMP") paid by wholesalers, taking into account all discounts and price reductions, for drugs in the "retail pharmacy class of trade." 42 U.S.C. § 1396r-8(k)(1).

53. The manufacturer's Medicaid rebate for brand-name drugs is the greater of: (1) 15.1% of the AMP or (2) the difference between the AMP and the manufacturer's nationwide "best price." 42 U.S.C. § 1396r-8(c)(1). Thus if any U.S. purchaser (with certain statutory exceptions) pays less than 84.9% of the AMP for the brand-name drug, the Medicaid rebate paid by the manufacturer will be based on that best price. The Medicaid rebate for generic and over-the-counter drugs is 11% of AMP. 42 U.S.C. § 1396r-8(c)(3).

COUNT I
VIOLATION OF COMMERCE CLAUSE
Section 2697(2)

54. Paragraphs 1-53 are incorporated by reference.

55. The Commerce Clause of the United States Constitution prohibits a state from regulating transactions occurring outside of the state.

56. The "anti-profiteering" provisions of the Act subject manufacturers to penalties with respect to prices, profits, and terms of sales occurring outside Maine.

57. These provisions (Section 2697(2)) violate the Commerce Clause.

58. PhRMA has no adequate remedy at law.

COUNT II
VIOLATION OF COMMERCE CLAUSE
Sections 2681(3) and 254 ss8-a

59. Paragraphs 1-58 are incorporated by reference.

60. The Commerce Clause of the United States Constitution prohibits a state from regulating transactions occurring outside of the state.

61. The rebate provisions of the Act effectively regulates the prices received by drug manufacturers from their customers in transactions occurring outside of Maine.

62. The rebate provisions (Sections 2681(3) and 254 ss8-A) violates the Commerce Clause.

63. PhRMA has no adequate remedy at law.

COUNT III
VIOLATION OF COMMERCE CLAUSE
Section 2681(4)

64. Paragraphs 1-63 are incorporated by reference.

65. The Commerce Clause prohibits a state from tying in-state prices to prices charged in other jurisdictions.

66. The rebate provision of the Act ties prices in Maine to prices paid in other jurisdictions by using as benchmarks for the Maine Rx program rebates the nationwide, federal Medicaid rebate, and nationwide rebates and discounts under other federal programs.

67. The rebate provision (Section 2681(4)) violates the Commerce Clause.

68. Plaintiff has no adequate remedy at law.

COUNT IV
VIOLATION OF COMMERCE CLAUSE
Section 2697(2)(D)

69. Paragraphs 1-68 are incorporated by reference.

70. The Commerce Clause prohibits a state from interfering with "the mobility of [interstate] commerce."

71. The "anti-retaliation" profiteering provision of the Act prohibits drug manufacturers from arranging their interstate distribution channels in response to the Act.

72. The "anti-retaliation" profiteering provision (Section 2697(2)(D)) violates the Commerce Clause.

73. PhRMA has no adequate remedy at law.

COUNT V
VIOLATION OF THE SUPREMACY CLAUSE
Sections 2681(7) and 3174-Y

74. Paragraphs 1-73 are incorporated by reference.

75. The Supremacy Clause prohibits state laws that conflict with federal laws and programs.

76. The prior authorization provisions of the Act conflicts with federal Medicaid law and the federal Medicaid program by curtailing Maine Medicaid beneficiaries' access to a manufacturer's drugs to punish its failure to finance discounts under the Maine Rx Program.

77. The prior authorization provisions (Sections 2681(7) and 3174-Y) violates the Supremacy Clause.

78. PhRMA has no adequate remedy at law.

COUNT VI
VIOLATION OF 42 U.S.C. § 1983

79. Paragraphs 1-78 are incorporated by reference.

80. The Commissioner and the Attorney General are State officials acting within the scope of their authority in implementing the Act.

81. The Act deprives Plaintiff's members of the rights, privileges, and immunities secured by the Commerce Clause and the Supremacy Clause of the U.S. Constitution.

82. The Commissioner and the Attorney General are liable to Plaintiff for proper redress under 42 U.S.C. § 1983.

RELIEF REQUESTED

WHEREFORE, Plaintiff, Pharmaceutical Research and Manufacturers of America respectfully requests the following relief:

A. A declaratory judgment, pursuant to 28 U.S.C. § 2201, that Sections 254 ss8-A, 2681(3), 2681(4), 2681(7), 2697, and 3174-Y of the Act violate the United States Constitution and are unenforceable;

B. A preliminary and permanent injunction enjoining the Defendants from implementing or enforcing the Act;

C. An order awarding PhRMA's costs and attorneys' fees pursuant to 42 U.S.C. § 1988; and

D. Such other and further relief as the Court deems just and proper.

Respectfully submitted,

/s/

Bruce C. Gerrity, Esq.
Ann R. Robinson, Esq.
Preti, Flaherty, Beliveau,
Pachios & Haley, LLC
45 Memorial Circle
P.O. Box 1058
Augusta, ME 04332-1058
(207) 623-5300

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Washington, DC 20004
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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MAINE

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA Plaintiff, v.	*	Civil Action No. _____
KEVIN CONCANNON, in his official capacity as Commissioner of the Department of Human Services for the State of Maine ANDREW KETTERER, in his official capacity as Attorney General for the State of Maine Defendants.	*	

DECLARATION OF RICHARD A. FELDMAN

1. My name is Richard A. Feldman. From December 1996 to present, I have served as the Executive Director, Trade and Pharmacy Affairs for Roxane Laboratories, Inc. (hereinafter "Roxane"), an affiliated company of Boehringer Ingelheim Pharmaceuticals, Inc. (hereinafter "Boehringer"). I am responsible for the retail distribution of product for both Roxane and Boehringer (collectively referred to as "Companies").

2. Boehringer is a corporation organized and existing under the laws of Delaware that maintains its principal place of business in Ridgefield, Connecticut.

3. Roxane is a corporation organized and existing under the laws of Delaware that maintains its principal place of business in Columbus, Ohio.

4. I am filing this Declaration in support of PhRMA's Motion for a Preliminary Injunction which seeks to enjoin the enforcement of the Act to Establish Fairer Pricing for Prescription Drugs, 2000 Me. Legis. Ch. 786 (S.P. 1026) (L.D. 2599) (West) (hereinafter, the "Maine Rx Law").

5. I am knowledgeable about Companies' distribution system, sales arrangements with wholesalers and other customers including the Federal government, and specifically, the extent of Companies' sales of prescription drugs in Maine.

6. With the exception of sales transactions described in paragraphs 7 and 8, sales of Companies' prescription drugs occur outside Maine. Companies' warehouses located in Columbus, Ohio and Reno, Nevada receive and fill orders from wholesalers, distributors and warehousing retail chains. The warehouses then ship the orders via common carrier to the requesting entity located at a location outside the state of Maine. Title to the prescription drugs passes to the wholesaler or distributor upon delivery to the carrier. The wholesalers, distributors and warehousing retail chains then sell the prescription drugs to retail stores located throughout the country, including the state of Maine. The wholesalers and distributors do not act on behalf of Companies in the resale of the prescription drugs.

7. Companies sell prescription drugs to one warehousing retail chain, Hannaford Brothers, in Scarborough, Maine. Companies ship the prescription drugs and send invoices directly to Hannaford Brothers.

8. Bindley Western Drug Company ("Bindley"), a wholesaler based in Indianapolis, Indiana, directs that Companies ship prescription drugs directly to its subsidiary, JE Gould, in Westbrook, Maine. However, Bindley is

invoiced and the title to the drugs shipped to JE Gould passes to Bindley.

9. Other than as described in paragraphs 7 and 8 of this declaration, Companies make no direct sales or shipments of prescription drugs in the State of Maine.

FURTHER DECLARANT SAYETH NOT.

I DECLARE UNDER PENALTY OF PERJURY THAT THE FOREGOING IS TRUE AND CORRECT.

DATED: August 8, 2000

/s/
Richard A. Feldman

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MAINE

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA
1100 Fifteenth Street, N.W.
Washington, DC 20005

Plaintiff,

v.

KEVIN CONCANNON, in his official capacity as Commissioner of the Department of Human Services for the State of Maine
221 State Street
Augusta, Maine 04333

ANDREW KETTERER, in his official capacity as Attorney General for the State of Maine
6 State House Station
Augusta, Maine 04333

Defendants.

* * * * * * *

Civil Action No. _____

DECLARATION OF RUSSEL A. BANTHAM

1. My name is Russel A. Bantham. From 1995 to present, I have served as Senior Vice-President and General Counsel of the Pharmaceutical Research and Manufacturers of America ("PhRMA").

2. I am filing this Declaration in support of PhRMA's Motion for a Preliminary Injunction which seeks to enjoin the

enforcement of the Act to Establish Fairer Pricing for Prescription Drugs, 2000 Me. Legis. Ch. 786 (S.P. 1026) (L.D. 2599) (West) (hereinafter, the "Act").

3. PhRMA is a non-profit corporation organized and existing under the laws of the State of Delaware. PhRMA's offices are located in Washington, D.C.

4. PhRMA represents the country's leading research-based pharmaceutical and biotechnology companies, which are devoted to inventing medicines that allow patients to lead longer, healthier, happier, and more productive lives. Together these companies account for over 75% of the sales of brand name drugs in the United States.

5. PhRMA serves as the pharmaceutical industry's principal policy advocate, representing its members' interests in matters before Congress, the Executive Branch, state regulatory agencies and legislatures, and the courts. PhRMA is committed to, *inter alia*, advancing public policies that foster continued innovation, educating the public about the drug development and discovery process, and promoting a fair and competitive marketplace. PhRMA has represented its members in connection with the Maine Legislature's consideration of legislation regulating prescription drugs, including the legislation ultimately enacted as the Act challenged here.

6. All of PhRMA's members have their principal places of business outside Maine.

7. PhRMA is authorized by its Board of Directors to bring this suit on behalf of its members. The regulation of prescription drug pricing is of vital concern to PhRMA's members.

FURTHER DECLARANT SAYETH NOT.

I DECLARE UNDER PENALTY OF PERJURY THAT THE FOREGOING IS TRUE AND CORRECT.

DATED: August __, 2000

/s/
Russel A. Bantham

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MAINE

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA Plaintiff, v.	*	Civil Action No. _____
KEVIN CONCANNON, in his official capacity as Commissioner of the Department of Human Services for the State of Maine ANDREW KETTERER, in his official capacity as Attorney General for the State of Maine Defendants.	*	

DECLARATION OF GEORGE BILYK

1. My name is George Bilyk. From August 1996 to present, I have served as the Senior Director, Medicaid and Medicare business of Janssen Pharmaceutica, Inc. ("Janssen"). Prior to my current position, I was Marketing Controller for Janssen from February 1992 until February 1994 and Managed Care finance controller from February 1994 until August 1996.

2. Janssen is a corporation organized and existing under the laws of Pennsylvania that maintains its principal place of business in Titusville, New Jersey. Janssen is a wholly

owned subsidiary of Johnson & Johnson, a New Jersey corporation that maintains its principal office in New Brunswick, New Jersey.

3. I am filing this Declaration in support of PhRMA's Motion for a Preliminary Injunction which seeks to enjoin the enforcement of the Act to Establish Fairer Pricing for Prescription Drugs, 2000 Me. Legis. Ch. 786 (S.P. 1026) (L.D. 2599) (West) (hereinafter, the "Maine Rx Law").

4. I am knowledgeable about Janssen's distribution system, including its sales arrangements with wholesalers and other customers including the Federal government, and specifically, the extent of Janssen's sales of prescription drugs in Maine. All sales of Janssen's prescription drugs occur outside Maine. Janssen's distribution center is located in Franklin, New Jersey from which it fills all orders from wholesalers and distributors. In accordance with Janssen's standard terms and conditions of sale pursuant to which it sells its products to its customers including wholesalers and distributors ("Terms and Conditions"), Janssen delivers the prescription drugs to its wholesalers and distributors at the loading dock of Janssen's distribution center in New Jersey and all sales are FOB, shipping point (i.e. Janssen's distribution center in Franklin, New Jersey). Title and risk of loss passes to the customer at the loading dock in New Jersey. A copy of Janssen's Terms and Conditions is attached to this declaration as Exhibit A. Wholesalers and distributors make payments in New Jersey for the prescription drugs purchased. Wholesalers and distributors re-sell Janssen's prescription drugs to their customers who are located throughout the country, including customers in the state of Maine. The wholesalers and distributors do not act on behalf of Janssen in the resale of the prescription drugs.

5. As far as I am aware only two customers, Bindley Western Drug Company and Progressive Distributors, Inc. operate warehouse and distribution facilities in Maine. However, once again, pursuant to Janssen's Terms and

Conditions its sales to these distributors take place in New Jersey.

6. When a prior authorization (a "PA") is required for a prescription drug under a plan providing prescription drug coverage, a physician must obtain specific permission from the plan each time the physician wishes to prescribe the drug, or the pharmacist must obtain specific permission from the plan each time the pharmacist is asked to fill a prescription for the drug. Imposition of a prior authorization requirement with respect to a particular drug severely curtails access to the drug for covered patients and sharply reduces the drug's market share and sales, as the PA causes a shift of patients to competing drugs of other manufacturers that are not subject to a PA. Because a PA imposes additional procedural burdens on physicians prescribing the manufacturer's drug and retail pharmacies dispensing it, the effect of a PA is to diminish the manufacturer's goodwill that helped foster demand for its drug over competing drugs produced by other manufacturers, and to shift physician and patient loyalty to those competing drugs, perhaps permanently.

7. Based upon Janssen's experience with PA's, if the Maine Department of Human Services imposes PA requirements on Janssen's prescription drugs in the Medicaid program pursuant to § 2681(7) of title 22 of the Maine Revised Statutes, patient access to those drugs will be sharply curtailed and the market share and sales of those drugs will be severely reduced, causing Janssen substantial injury. This injury resulting from a PA authorized by § 2681(7) while the PA is in place is certain to occur and is likely to be substantial.

8. Once market share is lost, it is difficult to recover and may never be recovered, as physicians and patients develop loyalty to competing manufacturers' prescription drugs not subject to the PA while the PA on the manufacturer's drug is in place. The result for the manufacturer whose drug is subject to the PA may be a permanent loss of sales, market

share, and good will. This lingering injury to a drug manufacturer resulting from a PA under § 2681(7) is certain to occur and is likely to be substantial.

9. On August 4, 2000 Janssen's sister company, Johnson & Johnson Health Care Systems, received the letter dated August 2, 2000 from Kevin W. Concannon, Commissioner of the State of Maine Department of Human Services, a true copy of which is attached to this declaration as Exhibit B.

FURTHER DECLARANT SAYETH NOT.

I DECLARE UNDER PENALTY OF PERJURY THAT THE FOREGOING IS TRUE AND CORRECT.

DATED: August 9, 2000

/s/
George Bilyk

[Exhibit A]

P.O. Box 401
Raritan, New Jersey
8869-0602

JANSSEN ORTHO-McNEIL Centocor
PHARMACEUTICA

Invoice

Bill To:

Ship To:

Purchase Order #	Invoice	Invoice Date	Terms of Payment	Due Date

NDC/UPC		Product Description	Quantity	Unit	Unit Price	Net Amount	Tax

Controlled Substance Schedule	DEA 222 Form	Customer DEA #	

Payments must be received in our bank by the Due Date In order to earn the discount.
Please mail your payments 3-5 days prior to the Due Date.
No Anticipation.
Post Audit claims will not be honored. A-061

TERMS AND CONDITIONS OF SALE

Any statement contained on any purchases order or similar document, which is not specifically approved or acknowledged in writing by Seller, will not be considered as part of the agreement between the parties.

All orders are subject to acceptance at the home office.

Title, Shipment, Delivery: Title to and Risk of loss of Seller's products passes to Purchaser upon delivery to a common carrier. Seller will pay the cost of freight and insurance to Purchaser's location. Purchaser will pay any costs due to special shipping requests. Seller reserves the right to make shipments in installments as it deems advisable or necessary, and all such installments shipped separately will be separately invoiced and paid.

Warranties

Seller warrants that: 1) No article bearing its name (or that of an affiliate) and covered by this invoice is adulterated or misbranded within the meaning of the Federal Food, Drug and Cosmetic Act, nor is an article which may not, under the provisions of sections 404 or 505 of such Act, be introduced into interstate commerce; 2) No article covered by this invoice is produced in violation of any provisions of the Fair Labor Standards Act on 1936, as amended; 3) The advertising claims, labels, and circulars employed by it do not violate any provisions of the Federal Trade Commission act, as amended. These warranties are in lieu of all other warranties, expressed or implied, including those of merchant ability and fitness for a particular purpose. At Seller's request, Buyer will return any allegedly defective products to Seller.

Limitation of Liability

In no event will Seller be liable for any direct, indirect, special or consequential damages arising out of or in

connection with the sale or use of products including, without limitation, damages resulting from any breach of any obligation imposed on Seller hereunder or in connection herewith. Consequential damages shall include, without limitation, loss of use, Income or profit, or loss or damage to person or property.

Invoicing and Pricing

An invoice is rendered by the Customer Service Department to cover each shipment. Merchandise is invoiced at prices in effect on the day the order is received. Prices are subject to change without notice. No claim for rebate on price declines is allowed, nor do we make claims on Buyer or our product on price advances.

All stated terms are from date of invoice, and payment must be received by the due date to earn the cash discount. Neither anticipation nor post audit claims are honored. To qualify for adjustments, report all discrepancies on this invoice within 15 days. No statement will be rendered; kindly remit from this invoice.

Taxes

Any tax, duty, custom or other fee of any nature imposed upon this transaction by any federal, state or local government authority shall be paid by Buyer in addition to the price quoted or invoiced. In the event Seller is required to prepay any such tax, Buyer will reimburse Seller.

Prescription Products

Any product named on this invoice and labeled "Caution: Federal law prohibits dispensing without prescription," is sold for such use only.

[Exhibit B]

Angus S. King, Jr.
Governor

Kevin W. Concannon
Commissioner

State Of Maine
DEPARTMENT OF HUMAN SERVICES
Augusta, Maine 04333

August 2, 2000

BARBARA DYMOND
JOHNNSON&JOHNSON HEALTH CARE SYSTEMS INC
1000 RT. 202 SOUTH
P.O. BOX 300
RARITAN, NJ 088690602

Dear BARBARA DYMOND,

I am writing to you on behalf of the State of Maine, Department of Human Services. I want to inform you about the new Maine Rx Program and invite you to participate in the rebate program for this initiative. I am enclosing a copy of the law, Public Law 1999, chapter 786, for your review.

The Governor and the Legislature passed this new law, during the past legislative session, which goes into effect on January 1, 2001. Under the Maine Rx program the State will serve as a pharmaceutical benefit manager (PBM) for the estimated 325,000 Maine residents who have no prescription drug benefit as part of a private or public health insurance program. Those residents would be eligible to receive a Maine Rx card.

The Maine Rx Program would provide your company's products to an ever growing population and a population that would exceed the current Medicaid population, which is currently 170,000 people. This means greater access to and utilization of your pharmaceuticals.

You will also find a rebate agreement enclosed. I am requesting you sign and return this agreement as soon as possible, but not later than November 1, 2000, so your company's products may be included in the Maine Rx Program for the January 1, 2001 start date. This law also addresses profiteering, unfair trade practices, and requires the Department impose prior authorization requirements in the Medicaid Program under this Title, as permitted by law, for the dispensing of prescription drugs provided by those manufacturers and labelers who do not enter into rebate agreements.

Also to be noted, the names of manufacturers and labelers who do not enter into rebate agreements pursuant to this law are public information. Your company has the opportunity to assist those Maine citizens with a real need for affordable prescription drugs. An added benefit to participating is your company gains nationwide recognition as a participant in the Maine Rx Program. This Program has received nationwide press attention and will continue to do so in the foreseeable future.

Thank you for your continued support of Maine Pharmacy Programs and for your concern for the prescription drug needs of all Maine citizens.

We look forward to working with you, and should you have any questions concerning this Program, feel free to call Jude Walsh, Director, Division of Quality Improvement at (207)287-1815 for our direct assistance.

Sincerely,

/s/
Kevin W. Conannon, Commissioner

Enclosures: PL 786
Rebate Agreement

MAINE RX PROGRAM REBATE AGREEMENT

BETWEEN

THE COMMISSIONER OF THE DEPARTMENT OF HUMAN SERVICES OF THE STATE OF MAINE

And -

THE MANUFACTURER IDENTIFIED IN SECTION VIII

OF THIS AGREEMENT

(Hereinafter referred to as the "Manufacturer")

The Commissioner, on behalf of the State of Maine, and the Manufacturer, on its own behalf for the purposes of complying with Public Law 1999, chapter 786, hereby agree to the following:

I. DEFINITIONS

The terms defined in this section will, for the purposes of this Agreement, have the meanings specified herein:

(a) "*AVERAGE WHOLESALE PRICE*" means the Wholesale Price charged on a specific commodity that is assigned by the drug Manufacturer and is listed in a nationally recognized drug-pricing file.

(b) "*CALENDAR QUARTER*" means four times a year. Specifically the first Calendar Quarter will be from January 1, 2001 — March 31, 2001. Each successive three-month period shall be a Calendar Quarter.

(c) "*COMMISSIONER*" means the Commissioner of the Department of Human Services.

(d) "*DEPARTMENT*" means the Department of Human Services.

(e) "*MANUFACTURER*" means the entity holding legal title or possession of the National Drug Code (NDC) for the Prescription Drug.

(f) "*NATIONAL DRUG CODE* (NDC)" is the identifying drug number maintained by the Food and Drug Administration (FDA). For the purposes of this Agreement, the complete 11-digit NDC will be used including the labeler code (which is assigned by the FDA and identifies the establishment), product code (which identifies the specific product or -formulation), and package size code to identify a prescription drug.

(g) "*NET SALES*" means Calendar Quarter gross sales revenue less cash discounts allowed and all other price reductions which reduce the actual price paid; and as discussed under the definition of WP.

(h) "*PRESCRIPTION DRUG*" means (1) legend drugs, defined as drugs carrying the statement "Caution: Federal Law Prohibits Dispensing Without A Prescription" and (2) any other drugs which by State law or regulation require the prescription of a licensed practitioner for dispensing. For purposes of this Agreement, all Prescription Drugs must be identified by the Manufacturer's labeler code segment of the National Drug Code (NDC).

(i) "*QUALIFIED RESIDENT*" means a resident of the State who has obtained from the Department a Maine Rx enrollment card.

(j) "*REBATE AMOUNT*" means the Medicaid Rebate amount.

(k) "*REBATE PAYMENT*" means, with respect to the Manufacturer's Prescription Drugs, the Calendar Quarter payment by the Manufacturer to the State of Maine

which shall be the sum of the Rebates of each prescription drug (computed for each dosage form and strength of each Prescription Drug) calculated as follows:

(1) The total number of Units paid under the Maine Rx Program for qualified residents during the Calendar Quarter multiplied by the Rebate amount per Unit.

(2) Effective January 1, 2001, a percentage equal to the Medicaid Rebate percentage to the State of Maine in effect for the corresponding time period.

(l) "*UNIT*" means drug Unit in the lowest identifiable amount (i.e. tablet or capsule for solid dosage forms, milliliter for liquid forms, gram for ointments or creams). The Manufacturer will specify the Unit for each dosage form and strength of each Prescription Drug in accordance with instructions developed by the Health Care Financing Administration for purposes of the Federal Medicaid Rebate program under Section 1927 of the Social Security Act.

(m) "*UTILIZATION DATA*" means the information regarding the total number of Units of each dosage form and strength of the Manufacturer's Prescription Drugs paid during the Calendar Quarter under the Program. Drugs dispensed prior to January 1, 2001 are excluded. The Utilization Data includes: (1) 11-digit NDC, including package size code; (2) product name; (3) quantity of Units paid during the Calendar Quarter by 11-digit NDC; (4) total number of prescriptions paid during the Calendar Quarter by 11-digit NDC; and (5) total dollar amount paid during the Calendar Quarter by 11-digit NDC.

(n) "*WHOLESALE PRICE* (WP)" means, with respect to a Prescription Drug of the Manufacturer for a Calendar Quarter the average price paid by Wholesalers in the United States to the Manufacturer, for ultimate

distribution to the retail pharmacy class of trade (excluding direct sales to hospitals, health maintenance organizations and to Wholesalers where the drug is relabeled under that distributor's national drug code). WP includes cash discounts allowed and all other price reductions, which reduce the actual price paid. It is calculated as a weighted average of prices for a Manufacturer's package sizes for each Prescription Drug by the Manufacturer during that Calendar Quarter. Specifically it is calculated as Net Sales divided by number of Units sold, excluding drugs or any other items given away but not contingent on any purchase requirements. For bundled sales, the allocation of the discount is made proportionately to the dollar value of the Units of each drug sold under the bundled arrangement. The V/P for a Calendar Quarter must be adjusted by the Manufacturer if cumulative discounts or other arrangements subsequently adjusted the prices actually realized.

(o) "*WHOLESALER*" means any entity (including a pharmacy or chain of pharmacies) to which the Manufacturer sells the Prescription Drug, but that does not re-label or repackage the Prescription Drug.

II. MANUFACTURER'S RESPONSIBILITIES

The Manufacturer agrees to the following:

(a) To calculate and to make a Rebate Payment each Calendar Quarter to the State of Maine for the Manufacturer's Prescription Drugs paid for by the Department pursuant to the Maine Rx Program during a Calendar Quarter under the Maine Rx Program as follows:

Manufacturer's first rebate payment for the Calendar Quarter January 1, 2001 through March 31, 2001 shall be due September 30, 2001, or 30 days after receipt of

utilization data pursuant to Section III (a) of this Agreement, whichever is later.

All subsequent Rebate payments will be made by the Manufacturer to the State of Maine within 30 days of the close of each Calendar Quarter, or within 30 days upon receipt of the Utilization. Data pursuant to Section III (a) of this Agreement, whichever is later. Simultaneously, with each Rebate Payment, the Manufacturer will provide the Department with the Manufacturer's most recent price catalog, unless no price changes were made from the previous Calendar Quarter.

(b) To continue to make a Rebate Payment to the State of Maine on all of its Prescription Drugs as defined in this Agreement so long as this Agreement, or a successor Agreement, is in force and as long as such Prescription Drugs are dispensed under the Manufacturer's NDC. If there are no sales by the Manufacturer during a Calendar Quarter the WP used for the most recent Calendar Quarter in which sales occurred will continue to be used in calculating Rebates.

(c) The Manufacturer will be responsible for Rebates on claims for prescription drugs that were dispensed within one year of the date that the claim was paid by the Department.

(d) The Manufacturer agrees to maintain all books, documents, papers, accounting records, and any other evidence pertaining to this Agreement and make such material available at its offices during normal business hours and shall send copies of such material to the Department upon the request of the Department during the period of this Agreement and for a period of two years after the termination of this Agreement. The Manufacturer shall allow inspection of pertinent documents by the Department or any authorized

representative of the State of Maine, and shall furnish copies thereof, if requested.

III. COMMISSIONER'S RIGHTS AND RESPONSIBILITIES

(a) The Department, on behalf of the Commissioner, shall send the Utilization Data as defined in this Agreement, to the Manufacturer, by certified mail, return receipt requested, within 60 days following the last day of each Calendar Quarter for qualified residents. The Commissioner, through the Department, shall maintain electronic claims records for the most recent four Calendar Quarters that will permit the Manufacturer to verify through an audit process The Utilization Data provided by the Department.

(b) The Department shall conduct audits, as it deems necessary to verify rebate calculation and payment.

IV. DISPUTE RESOLUTION FOR DISCREPANCIES IN REBATE AMOUNTS

Discrepancies in Rebate amounts must be resolved using the following process:

(a) If there is a discrepancy in the Manufacturer's or labeler's favor between the amount claimed by a pharmacy and the amount rebated by the Manufacturer or labeler, the Department, at the Department's expense, may hire a mutually agreed-upon auditor. If a discrepancy still exists following the audit, the Manufacturer or labeler shall justify the reason for the discrepancy or make payment to the Department for any additional amount due.

(b) If there is a discrepancy against the interest of the Manufacturer or labeler in the information provided by the Department to the Manufacturer or labeler regarding the Manufacturer's or labeler's Rebate, the Manufacturer or labeler, at the Manufacturer's or labeler's expense,

may hire a mutually agreed-upon independent auditor to verify the accuracy of the data supplied to the Department. If a discrepancy still exists following the audit, the Department shall justify the reason for the discrepancy or refund to the Manufacturer any excess payment made by the Manufacturer or labeler.

(c) Following the procedures established in paragraph a or b, either the Department or the Manufacturer or labeler may request a hearing before the Department of Human Services Administrative Hearings Unit. Supporting documentation must accompany the request for a hearing.

(d) The Manufacturer further agrees that the sole and exclusive means for the presentation of any legal claim against the State arising out of this Agreement shall be in accordance with 5 MRSA section 11001. The Manufacturer further covenants not to initiate legal proceedings in any State or Federal court in addition to, or in lieu of, proceedings under section 11001. This Agreement shall be governed in all respects by the laws, statutes, and regulations of the United States of America and of the State of Maine. The Manufacturer consents to personal jurisdiction in the State of Maine.

(e) Nothing herein shall be construed or interpreted as limiting or otherwise affecting the Department's ability to pursue its rights arising out of the terms and conditions of the Agreement in the event that a dispute between the parties is not otherwise resolved.

V. CONFIDENTIALITY PROVISIONS

(a) Commercial or financial information disclosed by the Manufacturer in connection with this Agreement is confidential information, and will not be disclosed by the Commissioner or the Department (including any auditors or agents thereof) in a form which discloses the identity of a specific Manufacturer or Wholesaler, prices

charged for drugs by such Manufacturer or Wholesaler, in accordance with 42 U.S.C. § 1396r-8(b)(3)(D), 22 M.R.S.A. § 402(3) and Maine Rules of Evidence, Rule 507.

(b) The Manufacturer will guarantee the protection and confidentiality of the Utilization Date, including the proper care, custody, use and preservation of records, papers, files, communications of the Department and any other information that may reveal information related to the Utilization Data. If the Manufacturer audits this information or receives further information on such data, that information shall also be held confidential. The Manufacturer shall have the right to disclose Utilization Data to auditors who agree to keep such information confidential.

(c) Notwithstanding the non-renewal or termination of the Agreement for any reason, the confidentiality provisions will remain in full force and effect.

VI. TERMINATION

(a) Unless otherwise terminated by either party pursuant to the terms of this Agreement, the Agreement shall be effective for an indefinite period beginning on January 1, 2001.

(b) The Manufacturer may terminate the Agreement for any reason, and such termination shall become effective the first day of the first Calendar Quarter period beginning sixty (60) days after the Manufacturer gives written notice requesting termination.

(c) The Commissioner may terminate the Agreement for any reason, upon sixty- (60) days prior written notice to the Manufacturer.

(d) The termination of this Agreement by either party will not affect any Rebate payments due to the State of Maine.

(e) In the event that any element of this Agreement is affected by a legislative amendment, including, but not limited to the percentage amount of Rebate required, such amended or revised provisions shall be incorporated by reference within this Agreement and shall supersede any of the conflicting provisions of this Agreement. If either party is unwilling to accept such a change in terms, this Agreement may be terminated pursuant to the terms set out in subsections (a) through (d) above.

VII. GENERAL PROVISIONS

(a) Any notice required to be given pursuant to the terms and provisions of this Agreement will be sent in writing.

Notice to the Commissioner will be sent to:

Maine Rx Program
Director of Pharmacy Programs
Bureau of Medical Services, 3rd Floor
11 State House Station
Augusta, ME 04333-0011

Notice to the Manufacturer will be sent to the address provided to the Department by the Manufacturer.

(b) In the event of a transfer of ownership of the Manufacturer, this Agreement is automatically assigned to the new owner subject to the conditions specified in this Agreement.

(c) Nothing in this Agreement will be construed to require or authorize the commission of any act contrary to law. If any provision of the Agreement is found to be invalid by a court of law, this Agreement will be construed in all respects as if any invalid or unenforceable provision were eliminated, without any effect on any other provision.

(d) Nothing in this Agreement shall be construed as a waiver or relinquishment of any legal rights of the Manufacturer or the Commissioner under the Constitution, the Social Security Act, other Federal laws or State laws.

(e) The terms "Department" and "Manufacturer" incorporate any contractors or agents thereof, which fulfill responsibilities pursuant to this Agreement unless specifically provided for in the Rebate Agreement.

(f) This Agreement will not be altered except by an amendment in writing signed by both parties and except as indicated in subsection VI (e). No person is authorized to alter or vary the terms unless the alteration appears by way of a written amendment, signed by a duly appointed representative of the Manufacturer, and the Commissioner, and approved by the Office of the Attorney General.

(g) In the event that a due date falls on a weekend, or a Federal or State holiday, the report or other item will be due on the first business day following that weekend or holiday.

VIII. MANUFACTURER'S ACCEPTANCE

I, _____ hereby agree to the terms
(Name of Authorized Representative)
of this Agreement for the following Manufacturer(s) and labeler(s):

_____ _____
(Labeler Name) (Code)

_____ _____
(Labeler Name) (Code)

_____ _____
(Labeler Name) (Code)

_____ _____
(Labeler Name) (Code)

_____ _____
(Signature) (Title)

Date: _____

IX. COMMISSIONER'S CERTIFICATION

This is to certify that _____ is a participant in the Maine Rx Program Rebate Program effective _____.

_____ _____

Christine Zukas-Lessard DATE: _____

Acting Director, Bureau of Medical Services
For the Commissioner

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MAINE

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA

Plaintiff,

v.

KEVIN CONCANNON, in his official capacity as Commissioner of the Department of Human Services for the State of Maine

ANDREW KETTERER, in his official capacity as Attorney General for the State of Maine

Defendants.

Civil Action No. _____

DECLARATION OF THOMAS M MCPHILLIPS

1. My name is Thomas M. McPhillips. I serve as the Senior Director of the U.S. Trade Group of Pfizer Inc. ("Pfizer").

2. Pfizer is a corporation organized and existing under the laws of Delaware that maintains its principal place of business in New York, New York.

3. I am filing this Declaration in support of PhRMA's Motion for a Preliminary Injunction which seeks to enjoin the enforcement of the Act to Establish Fairer Pricing for

Prescription Drugs, 2000 Me. Legis. Ch. 786 (S.P. 1026) (L.D. 2599) (West) (hereinafter, the "Maine Rx Law").

4. I am knowledgeable about Pfizer's distribution system, including its sales arrangements with wholesalers and other customers including the Federal government, and specifically, the extent of Pfizer's sales of prescription drugs in Maine.

5. With the exception of sales transactions described in paragraph 7, sales of Pfizer's prescription drugs occur outside Maine. The Pfizer warehouses located in New Jersey, Tennessee and California fill orders from wholesalers and direct customers. In accordance with its standard published terms of sales to wholesalers and direct customers a copy of which is attached as Exhibit A to this declaration, Pfizer receives orders from wholesalers and other customers by electronic medium, facsimile, mail or telephone at Pfizer's logistics center in Memphis, Tennessee and then routes the orders to appropriate warehouses for processing. The warehouses then ship the orders via common carrier to the customers. The terms of sale state that title to the prescription drugs passes to the wholesaler or direct customer upon delivery to the carrier which is when a sale is recognized. The wholesalers then sell the prescription drugs to their customers who are located throughout the country, including customers in the state of Maine. The wholesaler and distributors do not act on behalf of Pfizer in the resale of the prescription drugs. Direct customers include retail pharmacies, hospitals, public health clinics and other dispensing pharmacies. These customers dispense product based on physician's orders and prescriptions to patients located throughout the United States.

6. Warner Lambert Company is a wholly owned subsidiary of Pfizer. Warner Lambert's operating division, Parke-Davis sells prescription drugs outside of Maine. The Parke-Davis warehouses located in Illinois and Pennsylvania fill orders from wholesalers and direct customers. In accordance with Parke- Davis' standard terms of sales to wholesalers and

direct customers, Parke-Davis ships orders via common carriers to customers. Parke-Davis' terms of sale provide that the prescription drugs are shipped "FOB point of origin." Therefore, title to the products passes to the customers at Parke Davis' warehouses.

7. Pfizer's sales of prescription drugs pursuant to the Federal Supply Schedule are not conducted pursuant to the standard published terms of sale described in Exhibit A. Rather, the title to products sold pursuant to the Federal Supply Schedule passes to Pfizer's customer upon delivery to the customer.

8. On August 4, 2000, Pfizer received the letter dated August 2, 2000 from Kevin W. Concannon, Commissioner of the State of Maine Department of Human Services, a true copy of which is attached to this declaration as Exhibit B.

FURTHER DECLARANT SAYETH NOT.

I DECLARE UNDER PENALTY OF PERJURY THAT THE FOREGOING IS TRUE AND CORRECT.

DATED: August 9, 2000

/s/
Thomas M. McPhillips

[Exhibit A]

Pfizer U.S. Pharmaceuticals

Wholesaler Price List

Effective
January 11, 2000

A-078

General Offices:

PFIZER U.S. PHARMACEUTICALS
235 East 42nd Street, New York, New York 10017
(212) 573-2323

DISTRIBUTION CENTERS:

1999 N. Shelby Oaks Drive, Memphis, Tennessee 38134
100 Jefferson Road, Parsippany, New Jersey 07054
16700 Red Hill Avenue, Irvine, California 92714
Toll-Free Order Number (800) 533-4535

BEST AVAILABLE COPY

U.S. Pharmaceuticals

GENERAL INFORMATION: ORDERS AND CORRESPONDENCE

All orders, and any correspondence pertaining thereto, are to be sent to:

Pfizer Inc
Memphis Logistics Center
1855 E. Shelby Oaks Drive
Memphis, TN 38134
Attn: Pharmaceuticals Customer Service
(1-800-533-6535)

All orders, whether issued upon solicitation or not, are subject to acceptance and credit approval by the company. We reserve the right to restrict order quantities.

PRICES
All prices are submitted without offer.

TERMS OF SALE
2% 30 days N.O.I. (date of invoice) net 45 days.
Electronically — 2% 30 days N.O.I. (date of invoice) net 30 days.

MINIMUM ORDER/ORDER FREQUENCY
All orders totaling less than $100.00 net will be subject to a $5.00 service charge. Under both terms, payment must be in the bank on the discount date. Accounts are limited to two orders per week. Orders in excess of the maximum will be subject to a $5.00 service charge.

SHIPPING AND ROUTING
On orders where we pay transportation charges, we reserve the privilege of shipping the number of case sizes shown. Where special handling or routing is requested, the difference in transportation charges will be charged to the customer.

DELIVERY
All deliveries shall be made F.O.B. point of shipment. Title to the goods sold shall pass upon delivery of the goods to the carrier.

DAMAGE OR DELAY IN TRANSIT
If merchandise arrives in broken or damaged condition, insist upon the carrier's agent noting the damage or breakage on the delivery receipt. The transportation company acts as the agent of the purchaser, and we are not responsible for loss of, damage to, or delay regarding the goods after delivery to the carrier. We shall be pleased to make, when requested, in forwarding claims against the carrier, but we cannot assume the responsibility of collecting them.

RETURN GOODS POLICY
Products may be returned on the following basis:

I. Returnable Items: The following products are returnable by customers without prior approval:

A. Outdated and discontinued merchandise, in the original container and bearing the original label.
B. Product damaged in transit, subject to the above paragraph.
C. Material shipped in error by Pfizer.

Note: no refunds will be issued for merchandise returned more than 12 months beyond expiration.

II. Non-Returnable Items: Product other than that listed above is deleted as non returnable. This includes, but is not limited to:

A. In-store product.
B. Packages with label removed.
C. Repackaged product.
D. Products that have been in a fire, storeroom, basement, or similar site.
E. Products sold as a "non-returnable" basis.
F. Products received more than twelve months beyond the expiration date noted on the package. (Products may be returned for shortdate, but no credit will be issued.)
G. Merchandise purchased or otherwise obtained in violation of any Federal, State, or local law or regulation.
H. Merchandise destroyed or damaged from honorable causes such as fire, water, tornado, etc., and merchandise that has otherwise deteriorated due to conditions occurring after shipment and beyond the control of the manufacturer, such as improper storage, heat, cold, smoke, etc.

Note: The Company's determination as to the salvage, credit or exchange value of non-shootlist returned shall be final. The Company reserves the right to destroy returned merchandise without payment or liability.

III. Procedure for Returning Pfizer U.S. Pharmaceutical Group Products:

A. For all customers, returnable items may be returned without prior authorization by Company representatives. Whenever you wish to return these items, pack the material in a container suitable for shipment, and include a packing list that identifies each item being returned, the name and address of your company, and your Pfizer account number. All returns shall be made in compliance with all applicable Federal and State laws and regulations. Note: direct customers (i.e., those that purchase primarily through wholesalers), see note C1 and C2 for additional credit information.

The address for returns is:

Pfizer Inc
Memphis Logistics Center
1855 E. Shelby Oaks Drive
Memphis, TN 38134
Attn: Returns Goods

All products must be returned freight prepaid by the sender, using generally accepted shipment methods. Use a separate packing list for each carton to ensure completion and customer credit. Upon receipt of the merchandise and verification of the contents and condition of the merchandise, a credit memorandum will be issued as appropriate. Credit will be issued at the lower of:

1. existing or contract price in effect 12 months prior, or
2. the current replacement price, or
3. original purchase price.

Partial bottles may be returned, and credit will be issued in 10% increments to a maximum of 70% for any opened package.

B. Merchandise delivered to Non-Returnable may be considered for exchange or credit (in full or partial) in the case of unusual circumstances. Prior approval is required by authorized Company personnel.

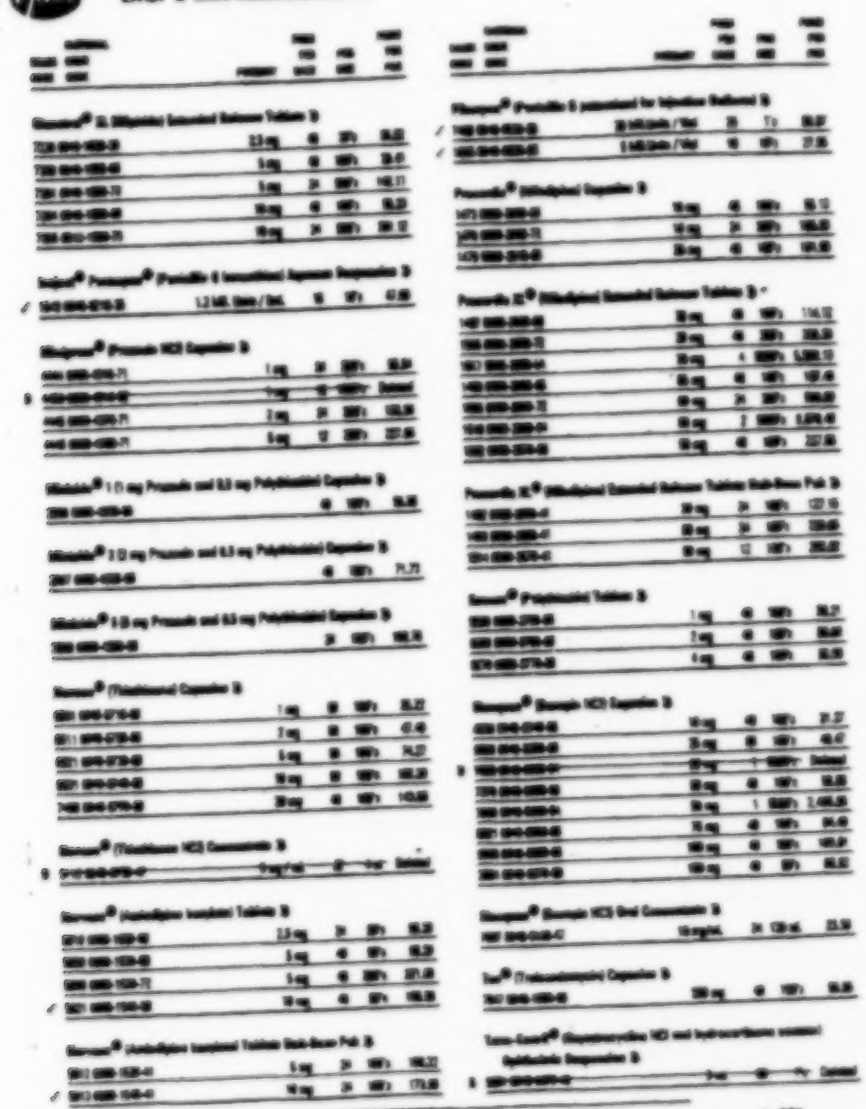
1. Customers with assigned Trade Development Managers should contact their Trade Development Manager.
2. All others should contact Customer Service at the aforementioned number listed above.

C. Additional information for specific types of customers:

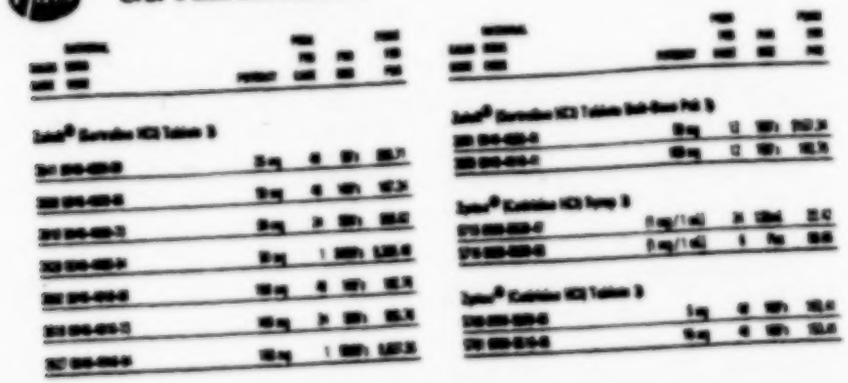
1. Hospitals, Clinics, Government Institutions, and other nonretail private entities: The Prescription Drug Marketing Act (PDMA) places specific restrictions on the return of pharmaceutical products from hospitals, healthcare entities and charitable institutions. The following applies to these entities to comply with the PDMA guidelines. If products were purchased from a wholesaler under a prime vendor contract, you may request that we issue a credit invoice to you through a specific wholesaler. If you choose this option, you must supply the following information with your request: your customer number, your hospital DEA number and/or HIN number, your buying group contribution memo, and the prime vendor wholesaler to receive credit. If product is were purchased at contract prices direct from Pfizer, then applicable credit will be issued to your direct account number, or to your preferred wholesaler if you supply the information requested above.

2. Non-Direct Retail Accounts: Customarily, returned goods are channeled through the source of purchase. However, returnable merchandise may be requested direct to Pfizer, and appropriate credit will be issued through your preferred wholesaler. In order to receive credit when returning merchandise, a non-direct account must list the merchandise being returned on a sheet of paper that identifies the pharmacy name, address and the desired wholesaler, name and address through which a credit invoice should be issued. Should no wholesaler be identified, Pfizer reserves the right to issue no credit. Pfizer cannot be responsible for the application of the credit from the wholesaler to the specific non-direct account.

U.S. Pharmaceuticals



U.S. Pharmaceuticals



Pfizer Pharmaceuticals Product Liability Protection Policy

In the event of a claim or lawsuit arising out of the dispensing of a Pfizer Pharmaceuticals product, it is Pfizer's policy to defend and hold harmless the pharmacist or the pharmacist's employer if the following conditions are met:

- If a prescription product, the prescription was properly filled by the pharmacist;
- the product was not improperly stored or packaged;
- there is no evidence of negligence or any improper or illegal act by the pharmacist or employer;
- the pharmacist has not made express warranties nor provided information inconsistent with the approved product labeling;
- the pharmacist and the pharmacist's employer, if any, provide Pfizer with prompt notice of the claim or lawsuit and fully cooperates with Pfizer in the defense of the claim or lawsuit.

Pfizer
235 East 42nd Street
New York, NY 10017

FIRST CLASS MAIL
U.S. POSTAGE
PAID
NEW YORK, NY
PERMIT NO.
4294

Pfizer U.S. Pharmaceuticals

Important Price Information

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MAINE

PHARMACEUTICAL RESEARCH
AND MANUFACTURERS OF AMERICA

Plaintiff,

v. Civil Action No. _____

KEVIN CONCANNON, in his official capacity as Commissioner of the Department of Human Services for the State of Maine

ANDREW KETTERER, in his official capacity as Attorney General for the State of Maine

Defendants.

DECLARATION OF JUDITH L. TEMPEL
IN SUPPORT OF PLAINTIFF'S MOTION
FOR PRELIMINARY INJUNCTION

1. My name is Judith L. Tempel. From May 1, 2000 to present, I have served as the Manager of Distribution Operations of Eli Lilly and Company ("Lilly").

2. Lilly is a corporation organized and existing under the laws of Indiana that maintains its principal place of business in Indianapolis, Indiana.

3. I have been an employee with Lilly for nine (9) years serving in various roles prior to my current position. I received my Masters in Civil Engineering from Purdue University in Indiana in 1990.

4. I am filing this Declaration in support of Plaintiffs Motion for a Preliminary Injunction which seeks to enjoin the enforcement of the Act to Establish Fairer Pricing for

Prescription Drugs, 2000 Me. Legis. Ch. 786 (S.P. 1026) (L.D. 2599) (West) (hereinafter, the "Maine Rx Law").

5. I am knowledgeable about Lilly's distribution system, including its sales arrangements with wholesalers and other customers including the Federal government, and specifically, the extent of Lilly's sales of prescription drugs in Maine.

6. All sales of Lilly's prescription drugs by Lilly occur outside Maine through direct, arms-length, transactions with authorized, independent wholesalers or distributors. Orders for all Lilly products from authorized wholesalers for distribution in the United States are filled for distribution from the Lilly warehouses located in Connecticut, Indiana and California. In accordance with the terms of Lilly's standard agreement with wholesalers ("Agreement"), the warehouse delivers the prescription drugs to the wholesalers or distributors on the loading dock of Lilly's warehouse. As is stated in the Agreement, title to the prescription drugs passes to the wholesaler or distributor upon delivery to the wholesaler or distributor at the Lilly warehouse. Wholesalers make payments for the prescriptions drugs purchased pursuant to the Agreement by electronic transfer to Lilly through Mellon Bank in Pittsburgh, Pennsylvania. Wholesalers and distributors sell the prescription drugs to their customers who are located throughout the country, including customers in the state of Maine, in separate, independent transactions. The wholesalers and distributors do not act on behalf of Lilly in the resale of the prescription drugs. From time to time, at the request of the wholesaler or distributor (or in the case of Lilly's growth hormone product, Humatrope®, the relevant health care facility or treating physician's office), Lilly may ship product directly to a particular end customer of a wholesaler or distributor, but the terms of the sale are governed by the same Agreement provisions, and the wholesaler or distributor are responsible for payment. Lilly's policy of selling its products in this manner has been in place for at least three (3) years.

7. On or about August 4, 2000, Lilly received the letter dated August 2, 2000 from Kevin W. Concannon, Commissioner of the State of Maine Department of Human Services, a true copy of which is attached to this declaration as Exhibit A.

FURTHER DECLARANT SAYETH NOT.

I DECLARE UNDER PENALTY OF PERJURY THAT THE FOREGOING IS TRUE AND CORRECT.

DATED: August 9, 2000

/s/

Judith L. Tempel
Manager of Distribution Operations
Eli Lilly and Company

[Exhibit A]

Angus S. King, Jr.
Governor

Kevin W. Concannon
Commissioner

State Of Maine
DEPARTMENT OF HUMAN SERVICES
Augusta, Maine 04333

August 2, 2000

RICHARD L. BROWN, MC255
ELI LILLY AND COMPANY
LILLY CORPORATE CENTER

INDIANAPOLIS, IN 46285

Dear RICHARD L. BROWN, MC255,

I am writing to you on behalf of the State of Maine, Department of Human Services. I want to inform you about the new Maine Rx Program and invite you to participate in the rebate program for this initiative. I am enclosing a copy of the law, Public Law 1999, chapter 786, for your review.

The Governor and the Legislature passed this new law, during the past legislative session, which goes into effect on January 1, 2001. Under the Maine Rx program the State will serve as a pharmaceutical benefit manager (PBM) for the estimated 325,000 Maine residents who have no prescription drug benefit as part of a private or public health insurance program. Those residents would be eligible to receive a Maine Rx card.

The Maine Rx Program would provide your company's products to an ever growing population and a population that would exceed the current Medicaid population, which is currently 170,000 people. This means greater access to and utilization of your pharmaceuticals.

You will also find a rebate agreement enclosed. I am requesting you sign and return this agreement as soon as possible, but not later than November 1, 2000, so your company's products may be included in the Maine Rx Program for the January 1, 2001 start date. This law also addresses profiteering, unfair trade practices, and requires the Department impose prior authorization requirements in the Medicaid Program under this Title, as permitted by law, for the dispensing of prescription drugs provided by those manufacturers and labelers who do not enter into rebate agreements.

Also to be noted, the names of manufacturers and labelers who do not enter into rebate agreements pursuant to this law are public information. Your company has the opportunity to assist those Maine citizens with a real need for affordable prescription drugs. An added benefit to participating is your company gains nationwide recognition as a participant in the Maine Rx Program. This Program has received nationwide press attention and will continue to do so in the foreseeable future.

Thank you for your continued support of Maine Pharmacy Programs and for your concern for the prescription drug needs of all Maine citizens.

We look forward to working with you, and should you have any questions concerning this Program, feel free to call Jude Walsh, Director, Division of Quality Improvement at (207)287-1815 for our direct assistance.

Sincerely,

/s/
Kevin W. Conannon, Commissioner

Enclosures: PL 786
Rebate Agreement

MAINE RX PROGRAM REBATE AGREEMENT

BETWEEN

THE COMMISSIONER OF THE DEPARTMENT OF HUMAN SERVICES OF THE STATE OF MAINE

And

THE MANUFACTURER IDENTIFIED IN SECTION VIII

OF THIS AGREEMENT

(Hereinafter referred to as the "Manufacturer")

The Commissioner, on behalf of the State of Maine, and the Manufacturer, on its own behalf for the purposes of complying with Public Law 1999, chapter 786, hereby agree to the following:

I. DEFINITIONS

The terms defined in this section will, for the purposes of this Agreement, have the meanings specified herein:

(a) "*AVERAGE WHOLESALE PRICE*" means the Wholesale Price charged on a specific commodity that is assigned by the drug Manufacturer and is listed in a nationally recognized drug-pricing file.

(b) "*CALENDAR QUARTER*" means four times a year. Specifically the first Calendar Quarter will be from January 1, 2001 — March 31, 2001. Each successive three-month period shall be a Calendar Quarter.

(c) "*COMMISSIONER*" means the Commissioner of the Department of Human Services.

(d) "*DEPARTMENT*" means the Department of Human Services.

(e) "*MANUFACTURER*" means the entity holding legal title or possession of the National Drug Code (NDC) for the Prescription Drug.

(f) "*NATIONAL DRUG CODE* (NDC)" is the identifying drug number maintained by the Food and Drug Administration (FDA). For the purposes of this Agreement, the complete 11-digit NDC will be used including the labeler code (which is assigned by the FDA and identifies the establishment), product code (which identifies the specific product or -formulation), and package size code to identify a prescription drug.

(g) "*NET SALES*" means Calendar Quarter gross sales revenue less cash discounts allowed and all other price reductions which reduce the actual price paid; and as discussed under the definition of WP.

(h) "*PRESCRIPTION DRUG*" means (1) legend drugs, defined as drugs carrying the statement "Caution: Federal Law Prohibits Dispensing Without A Prescription" and (2) any other drugs which by State law or regulation require the prescription of a licensed practitioner for dispensing. For purposes of this Agreement, all Prescription Drugs must be identified by the Manufacturer's labeler code segment of the National Drug Code (NDC).

(i) "*QUALIFIED RESIDENT*" means a resident of the State who has obtained from the Department a Maine Rx enrollment card.

(j) "*REBATE AMOUNT*" means the Medicaid Rebate amount.

(k) "*REBATE PAYMENT*" means, with respect to the Manufacturer's Prescription Drugs, the Calendar Quarter payment by the Manufacturer to the State of Maine

which shall be the sum of the Rebates of each prescription drug (computed for each dosage form and strength of each Prescription Drug) calculated as follows:

(1) The total number of Units paid under the Maine Rx Program for qualified residents during the Calendar Quarter multiplied by the Rebate amount per Unit.

(2) Effective January 1, 2001, a percentage equal to the Medicaid Rebate percentage to the State of Maine in effect for the corresponding time period.

(l) "*UNIT*" means drug Unit in the lowest identifiable amount (i.e. tablet or capsule for solid dosage forms, milliliter for liquid forms, gram for ointments or creams). The Manufacturer will specify the Unit for each dosage form and strength of each Prescription Drug in accordance with instructions developed by the Health Care Financing Administration for purposes of the Federal Medicaid Rebate program under Section 1927 of the Social Security Act.

(m) "*UTILIZATION DATA*" means the information regarding the total number of Units of each dosage form and strength of the Manufacturer's Prescription Drugs paid during the Calendar Quarter under the Program. Drugs dispensed prior to January 1, 2001 are excluded. The Utilization Data includes: (1) 11-digit NDC, including package size code; (2) product name; (3) quantity of Units paid during the Calendar Quarter by 11-digit NDC; (4) total number of prescriptions paid during the Calendar Quarter by 11-digit NDC; and (5) total dollar amount paid during the Calendar Quarter by 11-digit NDC.

(n) "*WHOLESALE PRICE* (WP)" means, with respect to a Prescription Drug of the Manufacturer for a Calendar Quarter the average price paid by Wholesalers in the United States to the Manufacturer, for ultimate

distribution to the retail pharmacy class of trade (excluding direct sales to hospitals, health maintenance organizations and to Wholesalers where the drug is relabeled under that distributor's national drug code). WP includes cash discounts allowed and all other price reductions, which reduce the actual price paid. It is calculated as a weighted average of prices for a Manufacturer's package sizes for each Prescription Drug by the Manufacturer during that Calendar Quarter. Specifically it is calculated as Net Sales divided by number of Units sold, excluding drugs or any other items given away but not contingent on any purchase requirements. For bundled sales, the allocation of the discount is made proportionately to the dollar value of the Units of each drug sold under the bundled arrangement. The V/P for a Calendar Quarter must be adjusted by the Manufacturer if cumulative discounts or other arrangements subsequently adjusted the prices actually realized.

(o) "*WHOLESALER*" means any entity (including a pharmacy or chain of pharmacies) to which the Manufacturer sells the Prescription Drug, but that does not re-label or repackage the Prescription Drug.

II. MANUFACTURER'S RESPONSIBILITIES

The Manufacturer agrees to the following:

(a) To calculate and to make a Rebate Payment each Calendar Quarter to the State of Maine for the Manufacturer's Prescription Drugs paid for by the Department pursuant to the Maine Rx Program during a Calendar Quarter under the Maine Rx Program as follows:

Manufacturer's first rebate payment for the Calendar Quarter January 1, 2001 through March 31, 2001 shall be due September 30, 2001, or 30 days after receipt of

utilization data pursuant to Section III (a) of this Agreement, whichever is later.

All subsequent Rebate payments will be made by the Manufacturer to the State of Maine within 30 days of the close of each Calendar Quarter, or within 30 days upon receipt of the Utilization Data pursuant to Section III (a) of this Agreement, whichever is later. Simultaneously, with each Rebate Payment, the Manufacturer will provide the Department with the Manufacturer's most recent price catalog, unless no price changes were made from the previous Calendar Quarter.

(b) To continue to make a Rebate Payment to the State of Maine on all of its Prescription Drugs as defined in this Agreement so long as this Agreement, or a successor Agreement, is in force and as long as such Prescription Drugs are dispensed under the Manufacturer's NDC. If there are no sales by the Manufacturer during a Calendar Quarter the WP used for the most recent Calendar Quarter in which sales occurred will continue to be used in calculating Rebates.

(c) The Manufacturer will be responsible for Rebates on claims for prescription drugs that were dispensed within one year of the date that the claim was paid by the Department.

(d) The Manufacturer agrees to maintain all books, documents, papers, accounting records, and any other evidence pertaining to this Agreement and make such material available at its offices during normal business hours and shall send copies of such material to the Department upon the request of the Department during the period of this Agreement and for a period of two years after the termination of this Agreement. The Manufacturer shall allow inspection of pertinent documents by the Department or any authorized

representative of the State of Maine, and shall furnish copies thereof, if requested.

III. COMMISSIONER'S RIGHTS AND RESPONSIBILITIES

(a) The Department, on behalf of the Commissioner, shall send the Utilization Data as defined in this Agreement, to the Manufacturer, by certified mail, return receipt requested, within 60 days following the last day of each Calendar Quarter for qualified residents. The Commissioner, through the Department, shall maintain electronic claims records for the most recent four Calendar Quarters that will permit the Manufacturer to verify through an audit process The Utilization Data provided by the Department.

(b) The Department shall conduct audits, as it deems necessary to verify rebate calculation and payment.

IV. DISPUTE RESOLUTION FOR DISCREPANCIES IN REBATE AMOUNTS

Discrepancies in Rebate amounts must be resolved using the following process:

(a) If there is a discrepancy in the Manufacturer's or labeler's favor between the amount claimed by a pharmacy and the amount rebated by the Manufacturer or labeler, the Department, at the Department's expense, may hire a mutually agreed-upon auditor. If a discrepancy still exists following the audit, the Manufacturer or labeler shall justify the reason for the discrepancy or make payment to the Department for any additional amount due.

(b) If there is a discrepancy against the interest of the Manufacturer or labeler in the information provided by the Department to the Manufacturer or labeler regarding the Manufacturer's or labeler's Rebate, the Manufacturer or labeler, at the Manufacturer's or labeler's expense,

may hire a mutually agreed-upon independent auditor to verify the accuracy of the data supplied to the Department. If a discrepancy still exists following the audit, the Department shall justify the reason for the discrepancy or refund to the Manufacturer any excess payment made by the Manufacturer or labeler.

(c) Following the procedures established in paragraph a or b, either the Department or the Manufacturer or labeler may request a hearing before the Department of Human Services Administrative Hearings Unit. Supporting documentation must accompany the request for a hearing.

(d) The Manufacturer further agrees that the sole and exclusive means for the presentation of any legal claim against the State arising out of this Agreement shall be in accordance with 5 MRSA section 11001. The Manufacturer further covenants not to initiate legal proceedings in any State or Federal court in addition to, or in lieu of, proceedings under section 11001. This Agreement shall be governed in all respects by the laws, statutes, and regulations of the United States of America and of the State of Maine. The Manufacturer consents to personal jurisdiction in the State of Maine.

(e) Nothing herein shall be construed or interpreted as limiting or otherwise affecting the Department's ability to pursue its rights arising out of the terms and conditions of the Agreement in the event that a dispute between the parties is not otherwise resolved.

V. CONFIDENTIALITY PROVISIONS

(a) Commercial or financial information disclosed by the Manufacturer in connection with this Agreement is confidential information, and will not be disclosed by the Commissioner or the Department (including any auditors or agents thereof) in a form which discloses the identity of a specific Manufacturer or Wholesaler, prices

charged for drugs by such Manufacturer or Wholesaler, in accordance with 42 U.S.C. § 1396r-8(b)(3)(D), 22 M.R.S.A. § 402(3) and Maine Rules of Evidence, Rule 507.

(b) The Manufacturer will guarantee the protection and confidentiality of the Utilization Date, including the proper care, custody, use and preservation of records, papers, files, communications of the Department and any other information that may reveal information related to the Utilization Data. If the Manufacturer audits this information or receives further information on such data, that information shall also be held confidential. The Manufacturer shall have the right to disclose Utilization Data to auditors who agree to keep such information confidential.

(c) Notwithstanding the non-renewal or termination of the Agreement for any reason, the confidentiality provisions will remain in full force and effect.

VI. TERMINATION

(a) Unless otherwise terminated by either party pursuant to the terms of this Agreement, the Agreement shall be effective for an indefinite period beginning on January 1, 2001.

(b) The Manufacturer may terminate the Agreement for any reason, and such termination shall become effective the first day of the first Calendar Quarter period beginning sixty (60) days after the Manufacturer gives written notice requesting termination.

(c) The Commissioner may terminate the Agreement for any reason, upon sixty- (60) days prior written notice to the Manufacturer.

(d) The termination of this Agreement by either party will not affect any Rebate payments due to the State of Maine.

(e) In the event that any element of this Agreement is affected by a legislative amendment, including, but not limited to the percentage amount of Rebate required, such amended or revised provisions shall be incorporated by reference within this Agreement and shall supersede any of the conflicting provisions of this Agreement. If either party is unwilling to accept such a change in terms, this Agreement may be terminated pursuant to the terms set out in subsections (a) through (d) above.

VII. GENERAL PROVISIONS

(a) Any notice required to be given pursuant to the terms and provisions of this Agreement will be sent in writing.

Notice to the Commissioner will be sent to:

Maine Rx Program
Director of Pharmacy Programs
Bureau of Medical Services, 3rd Floor
11 State House Station
Augusta, ME 04333-0011

Notice to the Manufacturer will be sent to the address provided to the Department by the Manufacturer.

(b) In the event of a transfer of ownership of the Manufacturer, this Agreement is automatically assigned to the new owner subject to the conditions specified in this Agreement.

(c) Nothing in this Agreement will be construed to require or authorize the commission of any act contrary to law. If any provision of the Agreement is found to be invalid by a court of law, this Agreement will be construed in all respects as if any invalid or unenforceable provision were eliminated, without any effect on any other provision.

(d) Nothing in this Agreement shall be construed as a waiver or relinquishment of any legal rights of the Manufacturer or the Commissioner under the Constitution, the Social Security Act, other Federal laws or State laws.

(e) The terms "Department" and "Manufacturer" incorporate any contractors or agents thereof, which fulfill responsibilities pursuant to this Agreement unless specifically provided for in the Rebate Agreement.

(f) This Agreement will not be altered except by an amendment in writing signed by both parties and except as indicated in subsection VI (e). No person is authorized to alter or vary the terms unless the alteration appears by way of a written amendment, signed by a duly appointed representative of the Manufacturer, and the Commissioner, and approved by the Office of the Attorney General.

(g) In the event that a due date falls on a weekend, or a Federal or State holiday, the report or other item will be due on the first business day following that weekend or holiday.

VIII. MANUFACTURER'S ACCEPTANCE

I, _____ hereby agree to the terms
(Name of Authorized Representative)
of this Agreement for the following Manufacturer(s) and labeler(s):

_____	_____
(Labeler Name)	(Code)
_____	_____
(Labeler Name)	(Code)
_____	_____
(Labeler Name)	(Code)

_____ _____
(Labeler Name) (Code)

_____ _____
(Signature) (Title)

Date: _____

IX. COMMISSIONER'S CERTIFICATION

This is to certify that _____ is a participant in the Maine Rx Program Rebate Program effective _____.

_____ _____

Christine Zukas-Lessard DATE: _____

Acting Director, Bureau of Medical Services
For the Commissioner

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MAINE

PHARMACEUTICAL RESEARCH
AND MANUFACTURERS
OF AMERICA,

Plaintiff

v. Civil Action No. ___

KEVIN CONCANNON, in his official
Capacity as Commissioner of the
Department of Human Services for
the State of Maine, and
ANDREW KETTERER, in his official
Capacity as Attorney General
for the State of Maine,

Defendants

AFFIDAVIT OF SCOTT HOWELL, M.D.
IN SUPPORT OF PLAINTIFFS
MOTION FOR A PRELIMINARY INJUNCTION

1. My name is Dr. Scott Howell. I am Vice President of National Accounts, Managed Care, SmithKline Beechham Corporation. An accurate copy of my resume is attached as Exhibit A to this Affidavit.

2. When prior authorization is required for a drug under a plan providing prescription drug coverage, a physician must obtain specific permission from the plan each time the physician wishes to prescribe the drug, or the pharmacist must obtain specific permission from the plan each time he or she is asked to fill a prescription for the drug. The purpose of requiring prior authorization is to limit the use of the drug.

3. Prior authorization is often employed by managed care organizations ("MCOs") to enforce a drug formulary and is

usually intended to limit the drugs to be prescribed by health care professionals. MCOs typically require health care professionals to obtain prior authorization from the MCO before prescribing a drug (1) to ensure proper use of prescription drugs with a high potential for inappropriate use, (2) to limit the use of prescription drugs with severe or life threatening side effects and/or drug interactions; and (3) to encourage the use of cost-effective medications without diminishing safety or efficacy.

4. Prior authorization is not supposed to be, and on information and belief has never been, utilized as a form of punishment and without considering safety, efficacy and the availability of other drugs. On information and belief, prior authorization has never been required for a drug under one prescription drug coverage, for the purpose of influencing the manufacturer's pricing behavior in another program. On information and belief, such a use of prior authorization—limiting access to the drug by patients who are covered by one program, in order to bring about lower prices for the drug to patients who are covered in another program—is unprecedented. This, however, in my opinion, is the obvious aim, and would be the inevitable effect, of the Maine Act challenged in this case.

5. Even when justified by the considerations described in paragraph 3, prior authorization does not come without a cost to the healthcare professional and the patient. Consequently, it is my opinion that application of the prior authorization process for the artificial punitive purpose contemplated by the Maine Act—unrelated to Medicaid patient care or even the administration of the Medicaid program—will impose significant and gratuitous burdens on Medicaid healthcare providers and patients, as a result of which those patients likely will not receive the safest and most efficacious drugs that they would otherwise receive. Unmoored from the considerations described in paragraph 3, it is my opinion that such prior authorization process will (1) lead to inappropriate

prescribing of medications for Medicaid patients, (2) needlessly burden doctors who treat Medicaid patients; and (3) cause unnecessary inconvenience for Medicaid patients.

6. In my opinion, prior authorization of drugs, without regard to safety or efficacy, will lead to drugs being prescribed that are less safe and efficacious. Healthcare professionals choose medicines for patients based on their understanding of their patients' needs and the efficacy and safety profile of the drugs. Prior authorization causes doctors to switch from first-choice drugs to potentially less safe and effective second-choice drugs. Even though healthcare professionals would not knowingly prescribe another drug that they expected to be ineffective or harmful to the patient, healthcare professionals would be forced to switch to drugs that have safety and efficacy profiles with which they are less familiar or may consider less desirable.

7. Suppose, for example, that, pursuant to the Maine Act, physicians in Maine were restricted from prescribing *Augmentin* for their Medicaid patients. *Augmentin*, a leading antibiotic used for ear infections in children, was recommended in national guidelines published by the CDC for such use. Less effective alternatives do exist, and if *Augmentin* were subject to prior authorization, then it is likely that Maine healthcare professionals would switch patients to these less effective drugs. They would do so believing in good faith that the patient will be cured. However, this will not be the case in some instances. Some patients will have resistant infections that withstood the less effective product; some will recover more slowly; and others will suffer complications needlessly.

8. An inappropriate implementation of prior authorization also needlessly burdens the healthcare professional. When physicians decide based upon their professional judgment that a drug, which is subject to prior authorization, is the best remedy for their patients, the physicians are required each time they choose to prescribe the drug to justify to the MCO

why that particular patient needs the drug and then to obtain the MCO's approval for that use. In this day of increasing burdens in healthcare, it is no small measure to unnecessarily add to the hassles of doctors. In fact, it harms them greatly and reduces time they can spend with their patients.

9. Such broad prior authorizations cause unnecessary hassles and anxiety for patients. In many instances, patients cannot immediately receive their prescriptions subject to this process. Patients many times are required to wait until the MCO approves it and must return to the pharmacy to retrieve the drugs if they are approved. Frequently, anxiety and confusion occurs with patients because they do not understand why the medicine their doctor chose for them has not been approved and requires a switch. This anxiety can be exacerbated in situations where the patient had used the drug previously. This, in turn, can lead to compliance problems for patients.

10. When prior authorizations are implemented properly, they can increase the clinical and cost-effectiveness of a drug formulary. When used wrongly, they cause harm to both patients and health professionals. Because of these sensitive factors, MCO's do not implement blanket prior authorizations without regard to safety, efficacy, and cost-effectiveness of the drugs. MCOs hire large pharmacy departments, convene formal committees with healthcare professionals, and seek outside expert advice to make such important decisions. The implementation of prior authorization under the Maine Act, by contrast, does not permit such a thoughtful process. Consequently, in my opinion, this will create a high likelihood that it will cause harm to patients and healthcare professionals.

11. Requiring prior authorization for SmithKline's drugs in the Medicaid program in Maine is likely to have an adverse effect on SmithKline's market share and sales beyond the Medicaid program. When physicians encounter an obstacle (such as prior authorization) to prescribing a drug under one

program or plan, the existence of that obstacle tends to discourage them from prescribing the drug even under programs or plans that do not impose such obstacles. Thus, for example, in our experience, the most restrictive formularies in an area become de facto formularies for the area generally. For that reason, the Maine Act would curtail access to SmithKline's drugs not only for Maine residents covered by the Medicaid program but for the general population of Maine covered by the Maine Rx Program, causing a correspondingly greater loss to SmithKline of market share and sales for the prior authorized drugs.

12. The foregoing is based on personal knowledge, other than that which is upon information and belief as described above.

I state under penalty of perjury that the foregoing is true and correct. Executed on August 9, 2000.

/s/
SCOTT HOWELL, M.D.

[Exhibit A]

HOWARD SCOTT HOWELL, MD, MBA

Home	861 Lesley Road Villanova, PA 19085 (610) 989-0949
Office	3FP0505, Three Franklin Plaza Philadelphia, PA 19101 (215) 751-7549
Personal	DOB: December 13, 1960 Married, one child

Education

Undergraduate Education 1979-1983	The University of Notre Dame B.S. with high honors Pre-professional Studies
Medical Education 1983-1987	The Ohio State University M.D. magna cum laude
Internship and Residency 1987-1990	The Duke University Medical Center Internal Medicine
Graduate Education 1994-1996	The Fuqua School of Business Duke University M.B.A., Fuqua Scholar
Board Certification	Internal Medicine
Licensure	Ohio

Work History

1997-Present	SmithKline Beecham Pharmaceuticals Philadelphia, Pennsylvania Director/Vice President, Managed Care Division
1993-1997	The Ohio State University Medical Center Columbus, Ohio Medical Director of Ambulatory Care
1990-1993	Henderson County Internists Hendersonville, North Carolina Private Practice, General Internal Medicine

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MAINE

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA

Plaintiff,

v.

KEVIN CONCANNON, in his official capacity as Commissioner of the Department of Human Services for the State of Maine

ANDREW KETTERER, in his official capacity as Attorney General for the State of Maine

Defendants.

Civil Action No. _____

AFFIDAVIT OF DAVID MOULES
IN SUPPORT OF PLAINTIFF'S
MOTION FOR A PRELIMINARY INJUNCTION

1. My name is David Moules. I am Vice President and Director, National Accounts, Managed Care Division, SmithKline Beecham Pharmaceuticals ("SmithKline"). I have responsibility for SmithKline's national account customers in Health Maintenance Organization, Pharmacy Benefit Manager, Institutional (Hospital/GPO, Long Term Care), and Federal Accounts business segments. An accurate copy of my resume is attached as Exhibit A to this Affidavit.

2. SmithKline manufacturers and markets pharmaceuticals, vaccines, over-the-counter medicines and health related consumer products. One of the world's leading healthcare companies, SmithKline employs 47,300 people worldwide with operations in 160 countries.

3. I am knowledgeable about SmithKline's distribution system, including its sales arrangements with wholesalers and other customers including the Federal government, and specifically the extent to which SmithKline sells its drugs in Maine.

4. Although drugs produced by SmithKline are sold in Maine, SmithKline itself does not sell any of its drugs in Maine. (SmithKline sells vaccines in Maine, but it is my understanding that these vaccines are not covered by the Maine statute at issue in this case. SmithKline also sells to federal facilities in Maine under the Federal Supply Schedule.) SmithKline sells its drugs to wholesalers/ distributors, which are independent companies in which SmithKline has no ownership or other financial interest. None of these wholesalers/distributors is headquartered in Maine, and none of them maintains any warehouses in Maine to which SmithKline currently ships any of its drugs. SmithKline instead sells its drugs to these wholesalers/ distributors in transactions in which the sale does not take place in Maine, but at locations outside of Maine where SmithKline delivers its drugs to common carriers that transport the drugs to the wholesalers'/distributors' Out of state warehouse.

5. Under the governing Wholesaler Distribution Agreement, an example of which is attached as Exhibit B to this affidavit, title passes from SmithKline to the wholesaler upon SmithKline' s delivery of the drug to the common carrier at SmithKline's Tennessee distribution facility. In accordance with the terms of the Agreement, the warehouse then ships the order via common carrier (*i.e.*, Roadway Express, Federal Express, UPS) to the wholesaler or

distributor at a location outside the state of Maine. Although SmithKline will replace drugs lost or damaged during shipment, once the drug is delivered, the risk of loss passes to the wholesaler or distributor at its delivery site outside of Maine.

6. The SmithKline warehouse located in Knoxville, Tennessee fills electronic orders from wholesalers and distributors. SmithKline does not earmark its drugs for sale in particular states. To the contrary, under the terms of the Agreement, the wholesaler is free to sell drugs it has purchased from SmithKline to any customer (*e.g.*, a retail pharmacy) located anywhere in the country. Wholesalers and distributors sell the drugs to their customers who are located throughout the country, including customers in the state of Maine. The wholesaler/distributor does not act on behalf of SmithKline in the distribution chain.

7. I am also knowledgeable about the impact that prior authorization has on SmithKline's market share and sales. It is my opinion that the Maine Act threatens drug manufacturers with prior authorization in the Medicaid program if they decline to enter into rebate agreements with the state under Maine Act, precisely because the proponents of the statute understand that prior authorization severely and perhaps permanently damages a drug's market share and sales, and that, from a manufacturer's standpoint, avoiding prior authorization would therefore be a powerful incentive to enter into rebate agreements with the state.

8. The purpose of requiring prior authorization is to limit the use of the drug. When a drug is subject to prior authorization under a plan or program providing prescription drug coverage, each time a physician prescribes the drug for a patient, the physician is required to justify doing so to the administrator of the plan or program, and the prescription will not be covered under the plan or program without the administrator's approval. The circumstance under which

prior authorization is typically required are described in the Affidavit of Dr. Scott Howell.

9. As four examples demonstrate, requiring prior authorization with respect to a manufacturer's drug severely curtails patient access to the drug and sharply reduces the drug's market share and sales as the prior authorization shifts patients to competing drugs of other manufacturers that are not subject to prior authorization.

10. *Augmentin*. Augmentin is SmithKline's flagship antibiotic product, indicated for the treatment of infections caused by susceptible strains of bacteria in conditions such as lower respiratory tract infections, otitis media, sinusitis, skin and skin structure infections, and urinary tract infections. Patient access to Augmentin was sharply curtailed in the Las Vegas, NV market, and Augmentin sales in that market sharply dropped, when a prior authorization was put in place by the largest managed care organization in the metropolitan statistical area (over 100,000 lives). When the prior authorization was imposed in the first quarter of 1999, Augmentin had a 49% market share. Its market share two quarters after the PA was implemented was 18%. The prior authorization thus resulted in a 60.9% loss in market share.. Since implementation of the prior authorization, market share and sales have been significantly reduced and have not recovered. As a result of the prior authorization, SmithKline's cumulative loss in sales revenue at this health plan for the first full quarter in which the prior authorization was in effect was approximately $272,000. *See* Exhibit C to this Affidavit.

11. *Paxil*. Paxil, another SmithKline product, is a selective seratonin reuptake inhibitor ("SSRI"), indicated for the treatment of depression, obsessive compulsive disorder, panic disorder, and social anxiety disorder. Patient access to Paxil was reduced, and Paxil market share and sales correspondingly fell, in numerous geographical areas when a prior authorization was imposed by a large national managed

care organization in the first quarter of 1997. When the prior authorization was imposed in the first quarter of 1997, Paxil had a 21% market share. Its market share two years later was 12%. The prior authorization thus resulted in a 41.8% loss of market share over the following eight quarters. As a result of PA, SmithKline's cumulative loss in sales revenue at this managed care organization over the eight quarters analyzed was approximately $7 million. See Exhibit D. Only after this customer merged with another company and the prior authorization was removed in the third quarter of 1999 did sales in those geographical areas begin to recover.

12. *Relafen*. Relafen is SmithKline's nonsteroidal anti-inflammatory drug product ("NSAID") indicated for acute and chronic treatment of signs and symptoms of osteoarthritis and rheumatoid arthritis. Patient access to Relafen was reduced, and Relafen's market share and sales correspondingly fell, in numerous geographies when a prior authorization was introduced by a large national managed care organization in the first quarter of 1998. When the prior authorization was imposed in the first quarter of 1998, Relafen had a 12.8% market share. Its market share two years later was 4.2%. The prior authorization resulted in a 67.2% loss of market share over the eight quarters after the time the prior authorization was implemented. Since implementation of the PA, sales and market share have been significantly reduced and have not recovered. As a result of the PA, SmithKline's cumulative loss in sales revenue at this managed care organization over the eight quarters analyzed was approximately $2.9 million. *See* Exhibit E.

13. *Avandia*. Avandia is SmithKline's oral antidiabetic product indicated for gylcemic control in patients with type 2 diabetes. Patient access to Avandia was reduced, and Avandia market share and sales correspondingly fell, when a prior authorization was implemented by a large managed care plan in March 2000. The prior authorization resulted in a

drop in market share of 46% just two months after the prior authorization was implemented. *See* Exhibit F.

14. It is SmithKline's experience that the injury caused by a prior authorization can linger even after the prior authorization is lifted. Market share, once lost, is difficult to recover and may never be recovered, as physicians and patients develop loyalty to competing drugs of other manufacturers not subject to the prior authorization while the prior authorization on the manufacturer's drug is in place. The result for the manufacturer whose drug is subject to the prior authorization may be a permanent loss of sales and market share and a permanent loss of good will.

I state under penalty of perjury that the foregoing is true and correct. Executed on August 9, 2000.

/s/
DAVID MOULES

[Exhibit A]

DAVID A. MOULES

PROFESSIONAL EXPERIENCE

SMITHKLINE BEECHAM
U.S. PHARMCEUTICALS – MANAGED CARE DIVISION:
April 1997 – Present

Vice President and Director, National Accounts

Member of the Managed Care Division leadership team with responsibility for the national account customers in the HMO, PBM, Institutional (Hospital/GPO, Long Term Care) and Federal Accounts business segments. Primary responsibilities include:

- Provide strategic direction for the "business segments" that are responsible for selling/servicing the National Account customers of SB Pharmaceuticals.
- Develop and implement strategies to achieve sales (gross and net) objectives.
- Oversee the development, implementation and execution of marketing/business plans for the National Account Business Segments.
- Collaborate with SB Pharmaceutical groups (Sales, Marketing, Contract Management, Medical Affairs, Legal, etc.) to ensure the development and delivery of contracts, programs, and services which meet customer needs and enhance customer relationships.
- Forecast, plan and develop business plan objectives and budgets.
- SB Pharmaceuticals "Senior Management" contact/liaison for National Account customers in the IMO, PBM, Institutional and Federal Accounts business segments.

- Recommend most appropriate organizational/operating policies and strategies to achieve desired results.
- Evaluate/approve contracting strategies designed to improve business segment sales and profitability results.
- Assist in the negotiation of key customer proposals and contract renewals.
- Facilitate the development of Managed Care National Accounts personnel by establishing and monitoring Major Business Objectives (MBO's) for each direct report (for performance and personal development).

SMITHKLINE BEECHAM
DIVERSIFIED PHARMACEUTICAL SERVICES: September 1994 – April 1997

Senior Vice President

Member of Diversified's Executive Management Team responsible for the strategic planning and overall management of existing and potential managed care (HMO) and non-managed care (e.g., employer, TPA, insurance, consumer) clients. Primary responsibilities included:

- Managing the sales process to meet new business and client retention objectives
- Implementing a sales organizational structure that allowed Diversified to meet business objectives
- Recruiting/training and managing a national sales organization
- Managing the financial aspects of the business to improve profitability

CIGNA HEAL THCARE: June 1987- September 1994

Sales Vice President: April 1992 - September 1994

Responsible for recruiting, training, and motivating a high performance sales force in order to achieve Division results in

revenue growth, profitability, membership growth, persistency and new firm growth. In addition, the position responsibilities included assisting in key sale opportunities; maintaining executive level contacts with customers and producers; developing and monitoring annual sales plans; analyzing competitive information and providing input on local market needs; executing the human resource management process; preparing budget and staffing plans; and, maintaining relationships with matrix partners.

Sales Director February 1991 - March 1992

In reporting to the Sales Vice President, I was responsible for the hiring, coaching, and training of sales representatives and other office staff. As a Sales Director in a District office, I had full responsibility for developing annual sales plans; overseeing the management of the book of business; executing the human resource management process; preparing and monitoring the budget and staffing plans; assisting in key sales situations; and, coordinating sales/service plans with matrix partners.

Group Marketing Executive: June 1987 - January 1991

Responsible for employee benefit sales and account management for medical, dental, disability and life insurance lines of business. In this role, I managed an existing book of business in excess of $50 million in premium revenue; and was responsible for broadening the base of business through sales of both existing accounts as well as new firms. In addition, I was accountable for developing relationships for CIGNA within the employee benefits brokerage/consulting community.

[Exhibit B]

SB
SmithKline Beecham
Pharmaceuticals

WHOLESALER DISTRIBUTION AGREEMENT

Agreement January 1, 1999, between SmithKline Beecham Pharmaceuticals, a division of SmithKline Beecham Corpcration (SB), Philadelphia, Pennsylvania 19101, and

_____ Company _____

including its branches referred to on the attached Exhibit A, with main offices located at

_____

WHOLESALER.

Pursuant to this Agreement, SB appoints WHOLESALER as a distributor for its selected pharmaceutical products. The parties hereto, intending to be legally bound, hereby agree as follows:

I. OBLIGATIONS OF SB:

A. Shipment and Pricing to WHOLESALER

SB shall sell to WHOLESALER and shall ship selected products to the above address and to addresses specified in Exhibit A, attached hereto and incorporated by reference. SB shall charge WHOLESALER for SB products in accordance with the WHOLESALER prices and policies shown itT the SB Wholesaler Price List plus all applicable Federal and State Taxes in effect on the date of SB's receict of order.

B. Special Contract Pricing

SB shall adjust the Net Wholesale Purchase Prices for SB products sold and shipped from WHOLESALER'S inventory under contract sales for which SB is the sole marketer and has provided Special Contract Prices to customers. Such adjustments shall be made in accordance with SB contract Policy and Procedure document SB's Contract Policies and Procedures attached to this Agreement as Addendum I and incorporated by reference.

C. Terms

Payment by Check

SB shall provide a cash discount of 2% off SB's invoices (~~after deduction of all SB authorized credit memos excluding tax and chargeback credit memos~~) for cash payments postmarked and mailed to SB no later than thirty (30) days from date of invoice. In the case of automatic shipments, SB shall provide a 2% cash discount when payment is postmarked and mailed within the time period specified on the invoice.

Payments by EFT (Electronic Funds Transfer)

SB shall provide a discount of 2% off SB's invoices (~~after deduction of all SB authorized credit memos excluding tax and chargeback credit memos~~) for electronic funds transfer value received no later than thirry-four (34) days (invoice terms, plus 4 days) from the date of invoice. In the case of automatic shipments, SB shall provide a 2% cash discount when payment is received within the time period specified on the invoice, plus 4 days.

D. Transportation Charge Prepayment

SB shall prepay all transportation charges on orders when routing is done at SB's discretion. If WHOLESALER requests special routing and SB approves of the routing which results in higher transportation cost than would be incurred as a result of the routing of SB's choice, then the difference in the transportation cost shall be borne by WHOLESALER.

E. Returns

SB shall accept for credit any SB products returned from WHOLESALER'S inventory. Returns of WHOLESALER'S stock will be credited at the price when purchased. In accordance with SB's existing practices, authorized credits for returns are subject to a 2% reduction for discounts taken from the original invoice price. (See Sections I(C) and II(A) for application of credits.) Except for returns resulting from shipping and/or ordering errors, SB will not accept any opened or unopened package returns taken back by the WHOLESALER from its customers. Freight charges that are a result of returns are the responsibility of the WHOLE-SALER. Furthermore, SB will not accept merchandise that has been altered by repackaging. All returns over $10,000 require prior approval by the SB Trade Account Manager or the Customer Satisfaction Consultant at 1-800-877-1158.

F. Product Recalls

SB shall compensate WHOLESALER for the expense incurred in performing all requested recall services. Such compensation Shall be limited to expenses incurred for recall services directly related to WHOLESALER'S inventory in WHOLE-

SALERS possession unless SB requests additional recall services in writing from WHOLESALER.

G. Product Liability Protection

SB shall guarantee that all SB products meet standards of identity, strength. quality and purity in their manufacture. If a claim is made against the WHOLESALER as a result of distributing an SB product. SB will, subject to the following conditions, provide legal defense—including the payment of all reasonable expenses and attorney fees—and assume any judgment liability. This guarantee is conditioned on SB being promptly notified of any claim, or the service of any complaint, and the full cooperation of the WHOLESALER, including complete access to all relevant records.

This protection does not apply if the claim results from any negligent, improper or illegal act, or failure to act on the part of the WHOLESALER, or if the Product had been repackaged or had not been properly stored, handled or distributed.

II. OBLIGATIONS OF WHOLESALER:

A. Payment for Products

WHOLESALER shall pay for all regular orders purchased by WHOLESALER, with payment to be received by SB no later than thirty (30) days for cash payments or thirty-four (34) days for EFT payments from the date of invoice, or in the case of automatic shipments or other extended billing purchases, within the terms specified on the invoice, plus four (4) days for EFT. As provided in I(C) above, SB will provide a 2% cash discount off SB's invoices (~~after deduction of selected credit memos described in the SB WHOLESALER Price List~~) for

cash payment received thirty (30) days and EFT payments received by thirty-four (34) days after date of invoice. In the case of automatic shipment purchased, SB will provide a 2% cash discount for payment received within the time period specified on the invoice statement, plus four (4) days for EFT. *All invoices must be paid in full under the terms specified above and no deductions, other than the cash discount, are permitted from SB invoices unless authorized by a prior credit memo.* Any late payments SB receives shall accrue interest at the maximum rate allowed by law.

B. Financial and Credit Position

WHOLESALER shall maintain an adequate financial condition satisfactory to SB and substantiate such a condition with audited financial statements or as otherwise requested by SB. If, in SB's judgment, at anytime before shipment, the financial condition of the WHOLESALER becomes impaired or unsatisfactory to SB, SB may require cash payment or appropriate security before shipment. If WHOLESALER experiences any event that adversely impacts its financial condition, including, for instance and without limitation, a loss of a significant contract, a write-off of a significant receivable or any event impacting 3% or more of WHOLESALER's revenues, net profits or working capital, WHOLESALER shall provide SB with written notice of such change in financial condition within 24 hours of its occurrence.

C. Payment of Unearned Cash Discounts

WHOLESALER shall reimburse SB for any cash discounts taken but not earned. SB will issue a second invoice for the Unearned Cash Discount for

which WHOLESALER shall make payment upon receipt of invoice.

D. Ordering

1. WHOLESALER shall transmit SB orders either direct or, if indirect, via Informatics Ordernet Clearinghouse, using the SB automated order entry system.

2. WHOLESALER shall place orders as follows:

   a. Not more than ~~four (4)~~ one stock orders transmitted within each ~~month~~ week, unless otherwise approved by SB in Philadelphia. Drop-shipments will be handled on an individual basis and must be approved by SB;

   b. Unlimited orders for new selected products, strengths or sizes (referred to below as new SB items) which WHOLESALER places during the first sixty (60) days after their introduction:

   c. Telephone orders only in emergencies, and limited to ten (10) line items with a limit of one case per line item. WHOLESALER will pay a charge of $35.00 for emergency orders; this charge will not apply to orders due to SB out-of-stock situation.

E. Inventory

1. WHOLESALER shall purchase exclusively from SB or an authorized distribution of SB or an authorized distributor of SB all requirements of SB products and maintain at all times an inventory of those SB MUST STOCK items designated in SB's then current Wholesale Price List, at such a level that WHOLE-SALER'S

total out-of-stocks for such line items will not exceed six (6) in any month. Intra-company transfers between distribution centers are allowable.

2. SB can request, at any time, information regarding inventory levels of any SB product. This information can be compiled from either computer records or actual physical inventory count by an authorized SB representative.

3. SB requires that WHOLESALER shall report as soon as reasonably possible their sales of SB products to IMS Health (DDD).

F. Services

1. WHOLESALER shall provide aggressive sales support for SB Products as well as the order-taking, question-answering and delivery services necessary to meet reasonable needs of customers for these products.

2. WHOLESALER shall credit applicable WHOLESALER Customers for products returned directly to SB by WHOLESALER'S customers for which SB has issued a return goods credit memo to WHOLESALER.

3. WHOLESALER shall provide prompt marketing and stocking of new SB items for customers.

G. Special Contract Pricing

1. WHOLESALER shall hold in confidence and not disclose, directly or indirectly, to any third party (other than the entity soliciting such quotations), any information concerning any Special Contract Prices quoted by either WHOLESALER or SB in bidding for a contract

sale, so long as a product award has not been issued by the party soliciting such quotations. (As in the case of any material breach, a violation of this provision shall constitute grounds for immediate termination as an SB distributor.)

2. WHOLESALER shall comply with the SB contracts SB's Contracts Policies and Procedures attached to this Agreement as Addendum I.

3. WHOLESALER shall provide SB with electronic chargeback owed to the WHOLESALER at the end of each week, month or quarter. SB will credit the WHOLESALER for such chargeback.

4. See attached insert.

H. Lawful Handling

1. With respect to SB products, WHOLESALER shall take such precautions as are necessary to prevent them from falling into the hands of those who may not lawfully possess or handle them, and fully comply with local, state and federal laws.

2. WHOLESALER shall maintain all federal, state and local registrations necessary for the lawful handling of all SB products and immediately notify SB of any denial, revocation or suspension of any such registration or any changes in the SB products which WHOLESALER is authorized to distribute.

3. WHOLESALER shall immediately report to SB any in-transit loss or shortage of SB products including controlled substances.

4. WHOLESALER shall report any administrative, civil or criminal action by local, state or federal authorities against WHOLESALER, its officers or employees, regarding alleged violations of the Controlled Substance Act of 1970, as amended or other comparable legislation, and shall provide SB with complete information concerning the disposition of such action.

I. Proper Handling and Storage

WHOLESALER shall handle and store SB products in a clean and orderly location and in a manner that will assure that the proper rotation and quality of such products are maintained. WHOLESALER shall comply with SB criteria on shipping products that require special handling. WHOLESALER shall allow SB to conduct a physical inspection of WHOLESALER's storage facilities at any time SB requests.

J. Substitution

WHOLESALER shall fill orders for SB products, only with SB products. WHOLESALER shall not substitute any orders for SB Products with product not manufactured by SB.

K. Transfer of Ownership—Change in Address

WHOLESALER shall notify SB of the terms and conditions of any transfer in majority ownership or control, or any change in address, at least thirty (30) days prior to such action.

L. Automatic Shipments

WHOLESALER shall accept automatic shipments of reasonable quantities of new SB items including those distributed on an extended billing basis. SB

reserves the right to determine the size of such shipments.

M. Claims

WHOLESALER shall report all claims within fourteen (14) days of the receiving date. Proper documentation must accompany the claim. Deductions on damaged goods, shortages or shipping errors will not be allowed. SB will issue credit to the WHOLESALER. Unless SB fails to provide credit within 30 days of notification by WHOLESALER.

N. Audit or Review and Payment of Prior Transactions

WHOLESALER must submit all requests for review or payment of prior transactions within twelve (12) months of the transaction date.

III. GENERAL PROVISIONS

A. All orders are subject to acceptance and approval by SB at its central Distribution Office in Philadelphia, Pennsylvania.

B. This Agreement may be terminated by either party immediately upon any material breach of the terms of this Agreement by the other.

C. Neither SB nor WHOLESALER shall be liable to the other for failing to do as agreed where such failure is the result of a strike or other labor disturbance, fire, flood, earthquake, storm, governmental action, or other reason beyond its control.

D. The relationship created by this Agreement is a buyer-seller relationship and not an agency relationship.

E. Title to products shipped to WHOLESALER will pass when delivered by SB to carrier.

F. In the event there is a shortage of any SB product, SB shall have the right to prorate such product among its WHOLESALERS in such a manner as it, in its sole discretion, deems to be in the public interest.

G. SB reserves the right to fill only as much of a WHOLESALER'S product order as SB, in its sole discretion (after conferring in, good faith with WHOLESALER), determines represents WHOLESALERS bona fide current requirements for such product, and SB may exercise such right whether or not it has announced a forthcoming price increase for such product.

H. This Agreement shall not be construed as limiting WHOLESALERS lawful right to choose such customers and charge such prices as WHOLESALER freely determines or as granting to WHOLESALER exclusive rights in any territory.

I. This Agreement may be changed or amended only in writing signed by duly authorized representatives of SB and WHOLESALER, and in the case of SB, only by a representative from its office in Philadelphia. All attachments and addenda to this Agreement are hereby incorporated by reference.

J. This Agreement shall not be assigned or otherwise transferred without SB's prior written consent.

K. This Agreement shall terminate automatically on December 31, 2000, or at any subsequent date specified in writing by SB. During its term, the Agreement may be terminated by either party on thirty days' written notice mailed to the other at the address set forth above.

L. Payment for SB products shipped but not invoiced at the time termination of this Agreement becomes effective and any outstanding invoices or advance chargeback credits shall become due immediately upon termination.

M. This Agreement supersedes all prior contracts. agreements and understandings between SB and WHOLESALER.

N. This Agreement shall be construed in accordance with, and governed by, the laws of the Commonwealth of Pennsylvania.

O. Terms of this Agreement apply to those distribution centers located in the Continential United States. Alaska and Hawaii.

P. Unauthorized deductions are in violation of this Agreement and will result in delayed shipments.

Q. During the term of this Agreement and for a period of one year thereafter, WHOLESALER shall maintain documentation of all sales of SB products, including documentation of the purchaser of such products and WHOLESALER's payment to SB for such products (together, the "Documentation"). SB shall have the right, upon reasonable prior written notice to WHOLESALER, to audit all Documentation at WHOLESALER's primary place of business during normal working hours for purposes of assuring the appropriateness of any and all payments made or reimbursement claimed and/or paid under this Agreement and to assess WHOLESALER's performance under this Agreement, and shall have the right to audit the systems and processes used by WHOLESALER to assure that sales and calculations are performed accurately in accordance with the terms of this Agreement. SB

agrees that such audits will only be conducted by SB employees or an authorized representative.

R. WHOLESALER represents and warrants that, to the best of its information and belief that the computer hardware and software systems used by WHOLESALER in supplying orders or other information to SB pursuant to this Agreement are, or shall be by ~~May~~ June 1, 1999, Year 2000 compliant, and that the continuity and quality of supply of orders or other information to SB will not be affected by the failure of WHOLESALER's systems due to any Year 2000 non-compliance. WHOLESALER shall provide any required additions or modifications to the design and performance specifications of WHOLESALER to ensure compliance with this warranty at no cost to SB. In addition to any other rights or remedies available to SB under this Agreement, WHOLESALER's obligation and SB's remedy for any breach of this warranty, or upon notification by WHOLESALER that the WHOLESALER's internal systems shall not be Year 2000 compliant by the date specified in this warranty, shall be, at SB's discretion, one or more of the following: 1) WHOLESALER shall take all reasonable steps to minimize the impact of any Year 2000 non-compliance by the WHOLESALER's internal systems on the continuity and quality of supply of orders or other information to SB, and shall afford SB at least equal priority with WHOLESALER's other preferred customers in maintaining the continuity and quality of supply of orders or other information to SB; 2) WHOLESALER shall make any necessary repairs or replacements to WHOLESALER's internal systems in order to correct the breach within 30 days of receiving written notice from SB to do the same; 3)

SB may revise or restrict WHOLESALER's credit line or require cash payment or appropriate security before shipment; and/or 4) SB may terminate this Agreement.

S. Nothing in this Agreement or the conditions of sale of product to WHOLESALER shall be construed as granting or implying the grant of any license under any patent or trademark rights or any other industrial property rights held by SB or any of its affiliates anywhere in the world outside of the U.S., and SB shall be entitled to exercise such patent or trademark rights and/or other industrial property rights to the fullest extent legally permissible at the time of such exercise. Unless authorized, no trademarks of which SB or any of its affiliates are proprietors or authorized users shall be applied to any goods originally supplied by them on removal from their original container except by a Pharmacist in the course of dispensing a prescription endorsed by a qualified medical practitioner to indicate the name of the product on the container, or by a medical practitioner dispensing their own prescriptions. In the case where a trademark was on the goods when originally supplied by them, this trademark shall not be altered, partly removed or partly obliterated. All subsequent purchasers shall be put on notice of these reservations and shall be required to put any further subsequent purchasers on like notice. In the case where trademark was [illegible] the goods when originally supplied by the WHOLESALER SB agrees to provide legal defense—including the payment of all expenses and attorney fees—and assume any liability for judgement based on any alleged breach of any such patent or trademark rights by WHOLESALER.

IN WITNESS WHEREOF, the parties hereto have executed this WHOLESALER DISTRIBUTION AGREEMENT as of the date set forth above.

WHOLESALER	SMITHKLINE BEECHAM PHARMACEUTICALS Division of SmithKline Beecham Corporation Philadelphia, Pennsylvania
/s/	/s/
By _____ Authorized Representative	By _____ Vice President and Director Trade & Pharmacy Affairs - U.S.
Title: President	
Date: July 19, 1999	Date: _____

ATTACHMENTS

Addendum I: Contract Policies and Procedures

EXHIBIT C Impact of Prior Authorization Augmentin Analysis					
Historical Share and Dollar Impact Analysis of a PA Placed on Augmentin at Regional MCO in Nevada					
Unit and DACON WeightedRx Average WAC	$ 80.00				
	Augmentin TRx's	Augmentin Plan Market Share	Percent Change in Market Share	Gross Revenue	Total Loss in Revenue with Flat Class Growth
3Q98	3900	46%		$ 312,00	
4Q98	4053	49%	6.5%	$ 324,240	
1Q99	3599	23%	-50.0%	$ 287,920	$ 36,320
2Q99	645	18%	-60.9%	$ 51,600	$ 272,640
Total Loss in Gross Revenue to Plan					$ 308,960
Percent Loss in Plan Market Share					-60.9%

Assumptions
TRx Quarterly data extrapolated from semester (6 month), quarterly, and monthly "Eagle" data streams. Eagle reports are formatted from plan level NDC retail audits.
Percent Loss in Plan Market Share = variance between 3Q98 and 2Q99 plan market shares
Gross Revenue calculated by multiplying TRx's by average price per indication treated.

EXHIBIT D
Impact of Prior Authorization
Paxil Analysis

Historical Share and Dollar Impact Analysis of a PA Placed on Paxil at National MCO

Unit and DACON WeightedRx Average WAC	$ 66.89				
	PAXIL TRx's	Paxil Plan Market Share	Percent Change in Market Share	Gross Revenue	Total Loss in Revenue with Flat Class Growth
1Q97	40452	21%		2,705,834	
2Q97	32883	17%	-20.7%	2,199,544	$ 506,290
3Q97	24354	15%	-29.9%	1,629,039	$ 1,076,795
4Q97	20805	14%	-32.3%	1,391,646	$ 1,314,188
1Q98	23811	14%	-35.4%	1,592,718	$ 1,113,116
2Q98	23979	14%	-35.2%	1,603,955	$ 1,101,879
3Q98	25668	13%	-36.8%	1,716,933	$ 988,902
4Q98	26070	12%	-41.8%	1,743,822	$ 962,012
Total Loss in Gross Revenue to Plan					$ 7,063,183
Percent Loss in Plan Market Share					-41.8%

Assumptions
TRx Quarterly data extrapolated from semester (6 month), quarterly, and monthly "Eagle" data streams. Eagle reports are formatted from plan level NDC retail audits.
Gross Revenue calculated by multiplying TRx's by Unit and DACON weighted price per month

EXHIBIT E Impact of Prior Authorization Ralafen Analysis					
Historical Share and Dollar Impact Analysis of a PA Placed on Relafen at Large West Coast based MCO					
Unit and DACON WeightedRx Average WAC	$ 63.36				
	Ralefen TRx's	Ralefen Plan Market Share	Percent Change in Market Share	Gross Revenue	Total Loss in Revenue with Flat Class Growth
4Q97	12993	12.8%		$ 823,236	
1Q98	12361	9.4%	-26.6%	$ 783,193	$ 40,044
2Q98	7856	6.6%	-48.%4	$ 497,756	$ 325,480
3Q98	6612	6.5%	-49.2%	$ 418,936	$ 404,300
4Q98	6372	6.3%	-50.8%	$ 403,730	$ 419,507
1Q99	6036	5.2%	-59.4%	$ 382,441	$ 440,796
2Q99	6036	4.9%	-61.7%	$ 382,441	$ 440,796
3Q99	6189	4.6%	-64.1%	$ 392,135	$ 431,101
4Q99	5664	4.2%	-67.2%	$ 358,871	$ 464,365
Total Loss in Gross Revenue to Plan					$ 2,966,388
Percent Loss in Plan Market Share					-67.2%

Assumptions
TRx Quarterly data extrapolated from semester (6 month), quarterly, and monthly "Eagle" data streams. Eagle reports are formatted from plan level NDC retail audits.
Gross Revenue calculated by multiplying TRx's by Unit and DACON weighted price per month

EXHIBIT F
Impact of Prior Authorization
Avandia Analysis

Historical Share and Dollar Impact Analysis of a PA Placed on Avandia at MCO Plan

Unit and DACON WeightedRx Average WAC	$ 87.49					
	Avandia TRx's	Avandia Plan Market Share	Percent Change in Market Share	Gross Revenue	Estimated Gross Sales without PA	Total Loss in Revenue with PA Disadvantage Avandia
Jan-00	325	61%		$ 28,434		
Feb-00	357	55%		$ 31,234		
Mar-00	452	36%	-34.5%	$ 39,545	$ 60,417	$ (20,871)
Apr-00	467	30%	-46.0%	$ 40,858	$ 75,663	$ (34,805)
Total Loss in Gross Revenue to Plan						$ (55,676)
Percent Loss in Plan Market Share						46.0%

Assumptions
Customer has a 70/30 Actos vs Avandia market share split with the PA disadvantaging Avandia
Avandia market share is restated to reflect a 2 product market.
Gross Revenue with PA calculated by multiplying TRx's by Unit and DACON weighted price per month.
Estimated Gross Sales without a PA is calculated by dividing TRx's by Avandia Market Share and multiplying that sum by a 55% market share and DACON weighted price per month.
Percent Loss in Plan market share calculated as a variance between Feb 2000 market share of 55% and April 2000 market share of 30%.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MAINE

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA, Plaintiff,	)	Civil Action No. 00-157-B
v.	)	
KEVIN CONCANNON, in his official Capacity as Commissioner of the Department of Human Services For the State of Maine	)	
ANDREW KETTERER, in his official capacity asAttorney General for the State of Maine	)	
Defendants.	)	

DEFENDANTS' ANSWER

The defendants, Kevin Concannon, Commissioner of the Department of Human Services for the State of Maine, and Andrew Ketterer, the Attorney General for the State of Maine, each named in their official capacities, by and through their counsel, the Attorney General for the State of Maine, answer Plaintiff's complaint as follows:

1. The allegations set forth in paragraph 1 of the complaint are legal in nature and do not require a response.

2. The Act speaks for itself. The allegations set forth in paragraph 2 of the complaint are legal in nature and do not require a response, but to the extend they require a response they are denied.

3. The Act speaks for itself. The allegations set forth in paragraph 3 of the complaint are legal in nature and do not require a response, but to the extend they require a response they are denied.

4. Defendants deny the allegations set forth in paragraph 4 of the complaint.

5. Defendants lack sufficient knowledge and information to form a belief as to the truth of the allegations set forth in paragraph 5 of the complaint.

6. Defendants lack sufficient knowledge and information to form a belief as to the truth of the allegations set forth in paragraph 6 of the complaint.

7. Defendants lack sufficient knowledge and information to form a belief as to the truth of the allegations set forth in paragraph 7 of the complaint.

8. Defendants lack sufficient knowledge and information to form a belief as to the truth of the allegations set forth in paragraph 8 of the complaint.

9. Defendants lack sufficient knowledge and information to form a belief as to the truth of the allegations set forth in paragraph 9 of the complaint.

10. Defendants admit the allegations set forth in paragraph 10 of the complaint.

11. Defendants admit the allegations set forth in paragraph 11 of the complaint.

12. Defendants admit the allegations set forth in paragraph 12 of the complaint.

13. Defendants admit the allegations set forth in paragraph 13 of the complaint.

14. The allegations set forth in paragraph 14 of the complaint are legal in nature and do not require a response.

15. The allegations set forth in paragraph 15 of the complaint are legal in nature and do not require a response.

16. The allegations set forth in paragraph 16 of the complaint are legal in nature and do not require a response.

17. Defendants deny the allegations set forth in paragraph 17 of the complaint, except defendants admit that the Act enacts a new Chapter 603, entitled "Prescription Drug Access," in Maine Rev. Stat. Ann. Title 22.

18. The Act speaks for itself. The allegations set forth in paragraph 18 of the complaint are legal in nature and do not require a response.

19. The Act speaks for itself. The allegations set forth in paragraph 19 of the complaint are legal in nature and do not require a response.

20. Defendants admit that Maine residents who do not have prescription drug coverage under other public or private program will qualify for the Maine Rx Program to be administered by the Department, and that the number of such residents is presently estimated at 325,000. Otherwise, the allegations set forth in paragraph 20 of the complaint are denied.

21. The Act speaks for itself. The allegations set forth in paragraph 21 of the complaint are legal in nature and do not require a response, but to the extent they require a response they are denied.

22. The Act speaks for itself. The allegations set forth in paragraph 22 of the complaint are legal in nature and do not require a response, but to the extent they require a response they are denied.

23. Defendants lack sufficient knowledge and information to form a belief as to the truth of the allegations set forth in paragraph 23 of the complaint.

24. Defendants lack sufficient knowledge and information to form a belief as to the truth of the allegations set forth in paragraph 24 of the complaint.

25. The Act speaks for itself. The allegations set forth in paragraph 25 of the complaint are legal in nature and do not require a response, but to the extent they require a response they are denied.

26. The Act speaks for itself. The allegations set forth in paragraph 26 of the complaint are legal in nature and do not require a response, but to the extent they require a response they are denied.

27. The Act speaks for itself. The allegations set forth in paragraph 27 of the complaint are legal in nature and do not require a response, but to the extent they require a response they are denied.

28. Defendants deny the allegations set forth in paragraph 28 of the complaint, except Defendants admit that on August 2, 2000 the Commissioner sent to pharmaceutical manufacturers a "Rebate Agreement" which defines the rebate amount being sought as equal to the Medicaid rebate, and that the Commissioner requested that executed Rebate Agreements be returned to the Department by November 1, 2000.

29. The Act speaks for itself. The allegations set forth in paragraph 29 for the complaint are legal in nature and do not require a response, but to the extent they require a response they are denied.

30. The Act speaks for itself. The allegations set forth in paragraph 30 of the complaint are legal in nature and do not require a response, but to the extent they do require a response they are denied.

31. Defendants deny the allegations set forth in paragraph 31 of the complaint.

32. The Act speaks for itself. The allegations set forth in paragraph 32 of the complaint are legal in nature and do not require a response, but to the extent they require a response they are denied.

33. The Act speaks for itself. The allegations set forth in paragraph 33 of the complaint are legal in nature and do not require a response.

34. The Act speaks for itself. The allegations set forth in paragraph 34 of the complaint are legal in nature and do not require a response, but to the extend they require a response, they are denied.

35. The Act speaks for itself. The allegations set forth in paragraph 35 of the complaint are legal in nature and do not require a response.

36. Defendants admit the allegations set forth in paragraph 36 of the complaint.

37. The relevant Acts speak for themselves. The allegations set forth in paragraph 37 of the complaint are legal in nature and do not require a response.

38. The Act speaks for itself. The allegations set forth in paragraph 38 of the complaint are legal in nature and do not require a response.

39. The Act speaks for itself. The allegations set forth in paragraph 39 of the complaint are legal in nature and do not require a response.

40. The Act speaks for itself. The allegations set forth in paragraph 40 of the complaint are legal in nature and do not require a response, but to the extent they require a response, they are denied.

41. The Act speaks for itself. The allegations set forth in paragraph 41 of the complaint are legal in nature and do not require a response, but to the extent they require a response they are denied.

42. The Act speaks for itself. The allegations set forth in paragraph 42 of the complaint are legal in nature and do not require a response.

43. The Act speaks for itself. The allegations set forth in paragraph 43 of the complaint are legal in nature and do not require a response.

44. The Act speaks for itself. The allegations set forth in paragraph 44 of the complaint are legal in nature and do not require a response.

45. The Acts speak for themselves. The allegations set forth in paragraph 45 of the complaint are legal in nature and do not require a response.

46. The Act speaks for itself. The allegations set forth in paragraph 46 of the complaint are legal in nature and do not require a response.

47. The "Medicaid" Act speaks for itself. The allegations set forth in paragraph 47 of the complaint are legal in nature and do not require a response.

48. The Omnibus Budget Reconciliation Act of 1990 speaks for itself. The allegations set forth in paragraph 48 of the complaint are legal in nature and do not require a response.

49. The "Medicaid" Act speaks for itself. The allegations set forth in paragraph 49 of the complaint are legal in nature anti do not require a response.

50. The "Medicaid" Act speaks for itself. The allegations set forth in paragraph 50 of the complaint are legal in nature and do not require a response.

51. The "Medicaid" Act speaks for itself. The allegations set forth in paragraph 51 of the complaint are legal in nature and do not require a response.

52. The "Medicaid" Act speaks for itself. The allegations set forth in paragraph 52 of the complaint are legal in nature and do not require a response.

53. The "Medicaid" Act speaks for itself. The allegations set forth in paragraph 53 of the complaint are legal in nature and do not require a response.

54. Paragraph 54 of the complaint merely incorporates the previous paragraphs by reference, and thus no response is necessary.

55. The allegations set forth in paragraph 55 of the complaint are legal in nature and do not require a response, but to the extent they require a response they are denied.

56. The allegations set forth in paragraph 56 of the complaint are legal in nature and do not require a response, but to the extent they require a response they are denied.

57. Defendants deny the allegations set forth in paragraph 57 of the complaint.

58. Defendants deny the allegations set forth in paragraph 58 of the complaint.

59. Paragraph 59 of the complaint merely incorporates the previous paragraphs by reference, and thus no response is necessary.

60. The allegations set forth in paragraph 60 of the complaint are legal in nature and do not require a response, but to the extent they require a response they are denied.

61. Defendants deny the allegations set forth in paragraph 61 of the complaint.

62. Defendants deny the allegations set forth in paragraph 62 of the complaint.

63. Defendants deny the allegations set forth in paragraph 63 of the complaint.

64. Paragraph 64 of the complaint merely incorporates the previous paragraphs by reference, and thus no response is necessary.

65. The allegations set forth in paragraph 65 of the complaint are legal in nature and do not require a response, but to the extent they require a response they are denied.

66. Defendants deny the allegations set forth in paragraph 66 of the complaint.

67. Defendants deny the allegations set forth in paragraph 67 of the complaint.

68. Defendants deny the allegations set forth in paragraph 68 of the complaint.

69. Paragraph 69 of the complaint merely incorporates the previous paragraphs by reference, and thus no response is necessary.

70. The allegations set forth in paragraph 70 of the complaint are legal in nature and do not require a response, but to the extent they require a response they are denied.

71. Defendants deny the allegations set forth in paragraph 71 of the complaint.

72. Defendants deny the allegations set forth in paragraph 72 of the complaint.

73. Defendants deny the allegations set forth in paragraph 73 of the complaint.

74. Paragraph 74 of the complaint merely incorporates the previous paragraphs by reference, and thus no response is necessary.

75. The allegations set forth in paragraph 75 of the complaint are legal in nature and do not require a response, but to the extent they require a response they are denied.

76. Defendants deny the allegations set forth in paragraph 76 of the complaint.

77. Defendants deny the allegations set forth in paragraph 77 of the complaint.

78. Defendants deny the allegations set forth in paragraph 78 of the complaint.

79. Paragraph 79 of the complaint merely incorporates the previous paragraphs by reference, and thus no response is necessary.

80. Defendants admit the allegations set forth in paragraph 80 of the complaint.

81. Defendants deny the allegations set forth in paragraph 81 of the complaint.

82. Defendants deny the allegations set forth in paragraph 82 of the complaint.

DEFENSES

1. Plaintiff's claims are barred by the Market Participation exception to the Commerce Clause.

2. Plaintiff's claims are not ripe.

3. Plaintiff's claims are not justiciable under Article III of the United States Constitution.

4. Plaintiff's complaint fails to state a claim or claims upon which relief may be granted.

5. Plaintiff lacks standing to bring the claims alleged in the complaint.

6. The defendants are sued in their official capacities. To the extent Plaintiff seeks damages, such an action is barred by the Eleventh Amendment and the doctrine of sovereign immunity.

Dated: September 11, 2000
Augusta, Maine

ANDREW KETTERER
Attorney General

/s/

by: Andrew S. Hagler
Assistant Attorney General
6 State House Station
Augusta, Maine 04333
(207) 626-3800
Attorney for the Defendants

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MAINE

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA

Plaintiff

v.

Civil Action No.
00-157-B

KEVIN CONCANNON, in his official capacity as Commissioner of the Department of Human Services For the State of Maine
and
ANDREW KETTERER, in his official capacity as Attorney General For the State of Maine

Defendants.

AFFIDAVIT OF TIMOTHY S. CLIFFORD, M.D.

TIMOTHY S. CLIFFORD, M.D., being duly sworn, deposes and says that the following is true and correct and based upon personal knowledge:

1. My name is Dr. Timothy S. Clifford. Since April, 1996, I have been the Medical Director for the Maine Bureau of Medical Services, which administers the state's Medicaid Program. I am also a practicing Family Physician in Bucksport, Maine with 15 years experience.

2. In my role as Medicaid Medical Director I decide, in conjunction with the Maine Medicaid Drug Utilization Review ("DUR") Committee, which drugs are to be prior authorized and under which conditions particular requests for prior authorization will be granted. I personally review all

drug prior authorization requests which require the clinical determination of a physician.

3. I have read the declaration submitted by Dr. Scott Howell on behalf of the plaintiff in this action.

4. I disagree with Dr. Howell's suggestion that, when a particular drug is subject to a prior authorization requirement, physicians and pharmacists must obtain permission each time that drug is prescribed or dispensed to a particular patient.

5. The Maine Medicaid program does not require a physician to seek permission each time they wish to prescribe a drug subject to a prior authorized requirement. For the vast majority of drugs with prior authorization requirements, an authorization obtained from my office will permit a pharmacy to dispense that drug to that patient for as many times as the physician finds medically necessary, within a 6-12 month period. A smaller percentage of other drugs with prior authorization requirements may be prescribed, as deemed necessary by the physician, within a 3 month period. Only if specifically requested by the physician will the authorization obtained from my office be limited to less than 3 months.

6. I also disagree with Dr. Howell's suggestion that the purpose of imposing a prior authorization requirement on the use of a particular drug is to limit the use of that drug.

7. The primary purpose of a prior authorization requirement is to ensure that a drug is not being used inappropriately.

8. I also disagree with Dr. Howell's suggestion that the Department will not address safety and efficacy concerns in administering the prior authorization mechanism of the Maine Rx Program. I further disagree with the suggestion that the Department will not consider the availability of alternative drugs in making the decision of whether to subject a particular drug to a prior authorization requirement. Finally, I disagree with Dr. Howell's conclusion that the Department's

implementation of the prior authorization mechanism of the Maine Rx Program will limit the access of Medicaid recipients to medically necessary drugs.

[9]. The Maine Medicaid Program always has considered, and the Maine Rx Program always will consider, the safety, efficacy and availability of other drugs in its implementation of the prior authorization process. The Department certainly will not subject any single-source drug that fulfills a unique therapeutic function to the prior authorization process, regardless of whether the manufacturers participates in Maine Rx Program by entering into rebate agreements. The Department has drafted proposed administrative rules governing the use of the prior authorization provision of the Maine Rx Program. These rules require that the determination of whether a particular drug should be subjected to a prior authorization requirement be made by physicians and pharmacists sitting on the Maine Medicaid Drug Utilization Review Committee. These rules also require that the determination of whether a particular drug should be subjected to a prior authorization requirement will be based firmly upon considerations of medical necessity, and in compliance with the State's responsibilities as the administrator of the Maine Medicaid Program.

[10]. I also disagree with Dr. Howell's statement that the Maine Rx Program prior authorization provision will be implemented so as to impose significant and gratuitous burdens on Medicaid healthcare providers and patients, and that patients will, as a result, be denied access to the safest and most efficacious drugs.

[11]. Physicians in Maine are already well acquainted with the extensive prior authorization programs of the four HMO/Insurance programs which collectively cover nearly half the state's residents. As explained above, in implementing the prior autnorization provision of the Maine Rx Program, the Department will ensure that physicians will

always be able to prescribe the safest and most efficacious drugs for their Medicaid patients.

[12]. I also disagree with Dr. Howell's statement that prior authorization requirements cause doctors to switch from first-choice drugs to potentially less safe and effective second-choice drugs. The fundamental fallacy of this statement is the notion that the so-called "first choice" drug is always the safest and the most effective drug in all situations. A number of studies and Drug Utilization Review Programs have disproved this wildly inaccurate claim. For example, our Maine's Drug Utilization Review Program sends out nearly 1,000 letters a month to physicians warning them of potentially dangerous drug/drug and drug/disease interactions on recent prescriptions they have written and of which they are often unaware. Furthermore, our pharmacy point of purchase claims processing system alerts pharmacists to thousands of other dangerous drug/drug interactions, thereby preventing the filling of dangerous prescriptions. Thus, whether or not a prior authorization requirement applies to a specific drug, the "first choice" is often not the best choice. In fact, a well designed prior authorization program can improve safety and insure that the "first choice" drug is used appropriately.

[13.]. I also disagree with the claims Dr. Howell makes on behalf of his company's drug, *Augmentin*. Specifically, I disagree with Dr. Howell's attempt to suggest that the Centers for Disease Control unequivocally recommends *Augmentin*, for the treatment of *otitis media*, or ear infections.

[14]. In truth, the Centers for Disease Control recommended the broad spectrum antibiotic, *Augmentin*, as a second line medication in the treatment of ear infections only after an attempt to treat the condition with *Amoxicillin*, a far less expensive, and more "narrow band" antibiotic, have failed.

[15]. I also disagree with Dr. Howell's suggestion that implementation of the prior authorization provision of the Maine Rx Program will not involve a thoughtful process designed to achieve safety, efficacy, and cost-effectiveness in the dispensing of prescription drugs to Medicaid recipients.

[16]. The Department has in place adequate safeguards to ensure the best clinical treatment and safety of Medicaid patients. The Department currently employs two (2) full time pharmacists, two (2) part-time pharmacists and it contracts for the additional specialized services of four (4) other pharmacists. An active Drug Utilization Review Committee exists and that committee, and the Department, actively solicit and receive the advice from a variety of Health Maintenance Organizations, state and federal government agencies and health care professionals. In contrast to prior authorization programs established by private insurers, our program must comply with a variety of State and Federal laws and regulations which are in place to ensure that Medicaid recipients receive the drugs which are for them medically necessary. Accordingly, implementation of the prior authorization provision of the Maine Rx Program will involve the same thoughtful process we have always employed to ensure safety, efficacy, cost-effectiveness, so as to benefit all Medicaid recipients.

Dated: 9/7/00

/s/
TIMOTHY S. CLIFFORD, M.D.

STATE OF MAINE
KENNEBEC, ss

Before me this day personally appeared Timothy S. Clifford, M.D., who being duly sworn, deposes and says that the statements in the above affidavit of same, are true.

/s/

Name of Notary Public:
Notary Public, State of Maine
My Commission Expires:

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MAINE

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA	*	
Plaintiff,	*	
v.	*	Civil Action
	*	No. 00-157-B
KEVIN CONCANNON, Commissioner Of Maine Department of Human Services	*	
ANDREW KETTERER, Attorney General State of Maine	*	
Defendants.	*	

* * * * * * *

AFFIDAVIT OF H. BURTT RICHARDSON, JR, M.D.

I, Burtt Richardson, being duly sworn, state as follows:

1. This affidavit is based upon my personal knowledge, information and belief.

2. My name is H. Burtt Richardson, Jr. I am a pediatrician and a Maine Medicaid provider. A current and accurate copy of my resume is attached as Exhibit A to this Affidavit.

3. I have been a Maine Medicaid provider for 22 years.

4. My practice can be broken down into the following categories: approximately 18% is Medicaid (including the Cub Care program); 30% is HMO (HealthSource, Blue Cross Blue Shield, etc.); 30% is insured with non-HMO's; 12% insured with high deductible (uninsured for primary care); and 10% are uninsured.

5. My practice ranks in the 72nd percentile of Maine pediatricians who treat Maine Medicaid children, in terms of the number of Medicaid-insured children seen per year.

6. I believe that most HMO's punish particular drug manufacturers who fail to negotiate competitive practices by disapproving certain drugs in their formularies.

7. The Maine Medicaid Program does not currently use the prior authorization of drugs to punish particular drug manufacturers for any reason.

8. I prescribe Augmentin as a second line drug after another drug, usually high dose amoxicillin, has failed to adequately treat an ear infection. Augmentin is 3 to 6 times as expensive as amoxicillin, and amoxicillin is effective in treating ear infections 80-85% of the time.

9. I know that some of my non-Medicaid patients cannot afford their medication. They have told me they were not able to purchase a prescription and they have asked for a less expensive alternative or a sample.

10. I have personally observed the parents of some of my non-Medicaid patients get my bill for service and show my bill to their children saying "see how much you cost us." I have observed that this scenario makes children feel guilty about being sick.

11. I welcome the Maine Rx Program law because it is attempting to reduce the price of drugs to some of my patients who do not have drug insurance benefits and who might otherwise not be able to afford medications.

12. I approve of the Maine Rx Program prior authorization procedure so long as the decision to put a prior authorization on particular drugs is clinically appropriate, feasible for a medical office, and accompanied by the assurance that all Maine Medicaid recipients have access to medically necessary drugs.

Dated: 9-7-00

/s/
H. Burtt Richardson, Jr., M.D.

Personally appeared before me this 7th day of September, 2000, the above-named H. Burtt Richardson, Jr., and made oath that the foregoing statements are true based upon his personal knowledge, information and belief.

Dated: 9/7/00

/s/
Notary Public/Attorney at Law

DONNA A. HEAVENER
Notary Public • State of Maine
My Commission Expires 2/13/07

[Exhibit A]

CURRICULUM VITAE

RICHARDSON, HENRY BURTT, JR., M.D., F.A.A.P.

Pediatrician
Winthrop Family Pediatrics Center
R.F.D. 3 Box 9
Winthrop, Maine 04364
Phone 207-377-2114

BORN: Passaic, New Jersey – November 20, 1934

CITIZENSHIP: U.S.A.

EDUCATION: Haverford College,
Haverford, Pennsylvania
Temple University School of Medicine,
Philadelphia, Pennsylvania

DEGREES: A.B., Haverford College—June 1956
M.D., Temple University—June 1960

POST GRADUATE TRAINING:

July 1960—June 1961 Rotating Internship—State University of New York,
Upstate Medical Center Hospitals,
Syracuse, New York

July 1961—June 1963 Residency in Pediatrics,
St. Christopher's Hospital for Children,
Philadelphia, Pennsylvania

September 1967—August 1968 USPHS Traineeship in Neurological and SensoryDisease (Mental Retardation),
Children's Diagnostic and Development Center,
Georgetown University Hospital,
Washington, D.C.

MEDICAL LICENSURE:

Pennsylvania—August 1961
District of Columbia—April 1968
Virginia—June 1971
Maine—July 1975

BOARD CERTIFICATION:

Diplomate American Board of Pediatrics—May 1965
Recertified June 1983

MILITARY SERVICE:

Captain, United States Air Force (Medical Corps);
Base Pediatrician, Davis Monthan AFB,
Tucson, Arizona,
July 1963—June 1965

APPOINTMENTS:

Chief of Medical Unit (Peru), The People-to-People Health Foundation, Incorporated (Project HOPE). Trujillo, Peru, August 1965—July 1967

Visiting Professor of Pediatrics, National University of Trujillo. Peru, August 1965—July 1967

Attending Pediatrician, Children's Hospital National Medical Center, September 1968—December 1975

Assistant Professor of Pediatrics, George Washington University School of Medicine, September 1968—July 1971

Associate Director, Program for Learning Studies, Children's Hospital National Medical Center, September 1970—September 1974

Associate Professor of Child Health and Development, George Washington University School of Medicine, July 1971—July 1977

Visiting Professor and Consultant in Ambulatory Pediatrics, University of Arizona College of Medicine, March & April, 1974

Associate Director, Pediatric Training Program, Children's Hospital National Medical Center, October 1974—July 1977

Senior Attending Pediatrician and Vice Chairman, Department of General Medicine, Children's Hospital National Medical Center, January 1976—July 1977

Adjunct Associate Professor of Child Health and Development, George Washington University School of Medicine, July 1977—June 1980

Consultant Pediatrician, The People-to-People Health Foundation, Incorporated (Project HOPE), Trujillo, Peru, July 1977—January 1978

Attending Pediatrician, Kennebec Valley Medical Center, Augusta, Maine, January 1978—to present

Pediatrician, Winthrop Area Medical Center, Winthrop, Maine, January 1978—July 1984

Pediatrician, Winthrop Family Pediatrics Center, Winthrop, Maine, July 1984—to present

SOCIETY MEMBERSHIP

Pima County Pediatric Society	1963—1965
Sociedad Pediatricia de Trujillo	1956—1968

American Academy of Pediatrics	1968—to present
Medical Society of the District of Columbia	1969—1978
Society for Neuroscience	1970—1978
Maine Medical Association	1978—1980; 1986—to present

INVESTIGATIVE EXPERIENCE:

Two studies were carried out between 1961 and 1963, one concerning the laboratory diagnosis and clinical management of salicylate intoxication with gradation of severity and the other concerning the two-year residency experience with in-patients classified according to disease category. Between 1963 and 1965, clinical investigations were carried out relating to (1) epidemic infection with coxsackie A-16, (2) coccidioidomycosis, (3) the treatment of acute otitis media, and (4) the diagnosis and therapy of acute promazine intoxication.

Between 1965 and 1967, four studies were carried out in Peru regarding health conditions in a shanty-town community. These involved (1) the prevalence of diarrhea in infants and young children, (2) the nutritional state of infants and children between 6 months and 6 years of age, (3) the dietary habits of children under 15 years of age, and (4) the socio-economic and sanitary conditions of 100 families. An additional report was prepared concerning the introduction of family medicine concepts into the curriculum of the clinical years in a Latin American medical school.

Investigative activities from 1967 to 1977 involved (1) the development of diagnostic approaches to young children with learning or vision problems; (2) the implementation of interdisciplinary services for children with learning problems in health and public school settings; (3) the development of training programs subject to systematic evaluation for professionals and non-professionals working in child health and development areas; (4) planning and evaluation of large

scale health and child development services in school-aged children; and (5) the planning and evaluation of house officer curriculum in general pediatrics and child development.

Since 1978, focus has been on the introduction of health promotion education into school health programs and into the private practice of pediatrics and the design, implementation and evaluation of a developmental pediatrics curriculum for residents as chairperson of a national task force. Since 1982, investigations have included the effectiveness of early educational intervention for handicapped children and practical approaches to the prevention of developmental disabilities.

PUBLICATIONS (Articles):

1. Richardson, H.B., Jr., and Leibovitz, A.: Hand, foot and mouth disease in children: an epidemic associated with Coxsackie virus A-16, Journal of Pediatrics 67: 6-12, 1968.
2. Richardson, H.B., Jr., Anderson, J.A., and McKay, B.M., Acute pulmonary coccidioidemycosis in children. Journal of Pediatrics 70: 376-382, 1967.
3. Medina, T., Javier, and Richardson, H.B., Jr.: Estudio de diarrhea en una poblacion de barrriada; prevalencia en infantes y ninos menores y uso de un metodo de tratamiento standard. (Study of diarrhea in a shanty-town population; prevalence in infants and small children and use of a standard treatment method.) Transacciones del V Congreso Peruano de Pediatria (April, 1966).
4. Bartalos, M., and Richardson, H.B., Jr., Aneusomy by recombination: a possible example involving E-18 chromosome. Acta Genetica Medica et Gemellologiae (Rome) 18: 117-124, 1969.
5. Christopolos, Florence, Costenbader, Frank D., Goldberg, Herman K., Mills, Jack, and Richardson H. Burtt, Jr., Symposium on Dyslexia. Bulletin of the Washington Hospital Center. Vol. 1, 1: 5-25, 1970.
6. Richardson, H. Burtt, Jr., and Ozer, Mark N.: Diagnostic evaluation of children with learning problems: role of the pediatrician. Clinical Proceedings, Children's Hospital National Medical Center, Vol. 26: 119-125, 1970.
7. Ozer, Mark N., Richardson, H. Burtt, Jr., Tannhauser, Miriam, and Smith, Cora: Diagnostic evaluation of children with learning problems: An Interdisciplinary Clinic Model. Clinical Proceedings, Children's Hospital National Medical Center, Vol. 26: 166-177, 1970.
8. Ozer, Mark N., and Richardson, H. Burtt, Jr.: The diagnostic evaluation of children with learning problems: a communication process. Childhood Education 244-247, 1972.
9. Ozer, Mark N., and Richardson, H. Burtt, Jr.: The diagnostic evaluation of children with learning problems: a "process" approach. Journal of Learning Disabilities, 88-92, 1974.
10. Richardson, H. Burtt, Jr., Guralnick, Michael J., and Tupper, Deborah B.: Training pediatricians for effective involvement with handicapped preschool children and their families. Mental Retardation, Vol. 16, 1: 3-7, 1978.
11. Richardson, H. Burtt, Jr., and Guralnick, Michael J.: Pediatric residents and young handicapped children: curriculum evaluation. Journal of Medical Education, Vol. 53: 487-492, 1978.
12. Guralnick, Michael J., Richardson, H. Burtt Jr., and Heiser, Karen E.: A curriculum in handicapping conditions for pediatric residents. Exceptional Children, Vol. 48, 383-346, 1982.
13. Bennett, Forrest C., Guralnick, Michael J., Richardson, H. Burtt, Jr., and Heiser, Karen E.: Teaching developmental

pediatrics to residents: effectiveness of a structured curriculum. Pediatrics 74: 514-522, 1984.

14. Guralnick, Michael J., Bennett, Forrest C., Heiser, Karen E., and Richardson, H. Burtt, Jr., Training future primary care pediatricians to serve handicapped children and their families. Topics in Early Childhood Special Education, Vol 6: 1-11, 1987.

15. Guralnick, Michael J., Bennett, Forrest C., Heiser, Karen E., Richardson, H. Burtt, Jr., and Shibley, R.E., Jr.: Training residents in developmental pediatrics: results from a national replication. Journal of Development and Behavioral Pediatrics, Vol. 8: 260-265, 1987.

16. Guralnick, Michael J., Heiser, Karen E., Eaton, A.P., Bennett, Forrest C., and Richardson, H. Burtt, Jr., and Groom, J.M.: Pediatricians' perceptions of the effectiveness of early intervention for at-risk and handicapped children. Journal of Developmental and Behavioral Pediatrics, Vol. 9: 12-18, 1988.

PUBLICATIONS (BOOKS):

1. *Pediatric Education and The Needs of Exceptional Children*. Guralnick, Michael J., and Richardson, H. Burtt, Jr., (Editors). Baltimore: University Park Press, 1980.

PUBLICATIONS (CHAPTERS):

1. Richardson, H. Burtt, Jr.: Relationship of research to health and educational services. Chapter in *Early Experience and Visual Information Processing In Perceptual and Reading Disorders*. (F.A. Young and D.B. Lindsley, Eds.) Washington, National Academy of Sciences, 1970, pp. 467-473.

2. Ozer, Mark N., and Richardson, H. Burtt, Jr.: "Diagnosis" in relation to children with learning problems: the use of models. Chapter in *Cybernetics Technique in*

Brain Research and the Educational Process. Washington, D.C., American Society for Cybernetics, 1973, pp. 90-102.

3. Guralnick, Michael J., Richardson, H. Burtt, Jr., and Kutner, Douglas R.: Pediatric education and the development of exceptional children. Chapter in Guralnick, Michael J., and Richardson, H. Burtt, Jr., *Pediatric Education and The Needs of Exceptional Children*. Baltimore, University Park Press. 1980 pp. 2-19.

4. Richardson, H. Burtt, Jr., and Guralnick, Michael J.: An evaluation strategy for pediatric rotations on the needs of exceptional children. Chapter in Guralnick, Michael J., and Richardson, H. Burtt, Jr., *Pediatric Education and the Needs of Exceptional Children*. Baltimore, University Park Press, 1980, pp. 129-135.

5. Richardson, H. Burtt, Jr., Guralnick, Michael J., Taft, Lawrence T., and Levine, Melvin D.: A comprehensive curriculum in child development and handicapping conditions. Prospects for design, implementation and evaluation. Chapter in Guralnick, Michael J., and Richardson, H. Burtt, Jr., *Pediatric Education and the Needs of Exceptional Children*. Baltimore, University Park Press, 1980. pp. 185-202.

6. Richardson, H. Brutt, Jr., and Guralnick, Michael J.: Physician education in developmental-behavioral pediatrics. Chapter in Levine, Melvin D., et al., *Developmental-Behavioral Pediatrics*. Philadelphia, W.B. Saunders and Co., 1983, pp. 1210-1219.

7. Richardson, H. Burtt, Jr.: Pediatrics and developmental disabilities: the state of the art in pediatrics. Chapter in *Alliances in Health and Education for Disabled Children and Youth: Directions for the 80's*. Washington, D.C., American Society of Allied Health Professionals 1983.

8. Guralnick, Michael J., Heiser, Karen E., Bennett, Forrest C., and Richardson, H. Burtt, Jr.: A systems approach to training pediatricians in the field of developmental disabilities. In M.D. Powers (Ed.), *Severe Developmental Disabilities: Expanded Systems of Interaction*. Baltimore, Brookes. 1987, pp. 255-271.

9. Bennett, Forrest C., Guralnick, Michael J., Heiser, Karen E., and Richardson, H. Burtt, Jr.: Training in developmental pediatrics. In M.L. Wolraich and D.K. Routh (Eds.), *Advances in Developmental and Behavioral Pediatrics*. (Vol. 8) Greenwich, CT: JAI Press. 1987, pp. 99-124.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MAINE

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA

Plaintiff

v. Civil Action No. 00-157-B

KEVIN CONCANNON, in his official capacity as Commissioner of the Department of Human Services For the State of Maine
and
ANDREW KETTERER, in his official capacity as Attorney General For the State of Maine

Defendants.

AFFIDAVIT OF KEVIN CONCANNON

KEVIN CONCANNON, being duly sworn, deposes and says that the following is true and correct and based upon personal knowledge:

1) My name is Kevin Concannon. I am the Commissioner of the State of Maine Department of Human Services (the "Department"). I submit this affidavit in opposition to the plaintiff's motion for a preliminary injunction in the above-captioned action.

2) Title 22 M.R.S.A. §2681, et seq., assigns to the Department the responsibility of administering the newly enacted Maine Rx Program, a program designed to make prescription drugs more affordable for residents of Maine who do not otherwise have prescription drug benefits through

private insurance or public medical assistance programs. The program will commence on January 1, 2001.

3) While the precise number of Maine residents who will be eligible to enroll in the Maine Rx Program is not known at this time, the current Department estimate is that 325,000 persons may be eligible to enroll in the program.

4) Title 22 M.R.S.A. §2681(4) instructs the Commissioner of the Department to negotiate with drug manufacturers and labelers for drug rebates to be paid into the Maine Rx Program. In furtherance of that mandate, on August 2, 2000 I sent the Department's proposed Maine Rx Program Rebate Agreement ("Rebate Agreement") to manufacturers of prescription drugs. A copy of the Rebate Agreement is attached to this affidavit as exhibit A.

5) As is set forth in Section II of the Rebate Agreement, the first Maine Rx Program rebate payment from participating manufacturers, for drugs dispensed through the program during the first quarter of its operation will be due no earlier than September 30, 2001.

6) As of today, twenty-seven (27) prescription drug manufacturers have elected to participate in the Maine Rx Program by executing Maine Rx Program Rebate Agreements.

7) The Bureau of Medical Services is the branch of the Maine Department of Human Services charged with overseeing and administering the Medicaid Program.

8) 22 M.R.S.A. §2681(7) instructs the Department to impose prior authorization requirements in the Medicaid program, as permitted by law, for the dispensing of prescription drugs provided by manufacturers and labelers which do not enter into Maine Rx Rebate Agreements.

9) The Department will not impose a prior authorization requirement in the Medicaid program, pursuant to 22 M.R.S.A. §2681(7), where the imposition of such a

requirement would conflict with the requirements of the Medicaid program. Prior authorization requirements will not be implemented so as to prevent Medicaid recipients from obtaining medically necessary prescription drugs.

10) The Department is in the process of drafting administrative rules for the Maine Rx Program and drafting proposed amendments to the Medicaid rules. These new rules, and rule amendments, will be proposed according to the procedures set forth in the State of Maine Administrative Procedures Act. A copy of the current draft of the portion of the rules involving implementation of Maine Rx Program "prior authorization" provision are attached to this affidavit as exhibit B.

11) Pursuant to these proposed rules, Maine's Medicaid Drug Utilization Review Committee ("DUR Committee"), an advisory board comprised of physicians and pharmacists who are licensed to prescribe or dispense medications in Maine, will make the final determination of the clinical appropriateness of any recommendation that a prior authorization requirement be imposed with respect to a particular prescription drug manufactured by a manufacturer which has not entered into a Maine Rx Rebate Agreement. In making its determination of whether or not a prior authorization requirement is clinically appropriate, the DUR Committee shall be guided by the law of Medicaid, and particularly the principle that Medicaid recipients shall be assured access to all medically necessary prescription drugs.

12) The State of Maine purchases large quantities of prescription drugs on behalf of Medicaid recipients. A chart prepared by the Department which summarizes the State's drug purchasing activity in the Medicaid program over that last three fiscal years is attached to this affidavit as exhibit C.

Dated: September 8, 2000

/s/
KEVIN CONCANNON, COMMISSIONER

STATE OF MAINE
KENNEBEC, ss

Before me this day personally appeared Kevin Concannon, who being duly sworn, deposes and says that the statements in the above affidavit of same, are true.

/s/ Marie Lahaye
Name of Notary Public
Notary Public, State of Maine
My Commission Expires: 1-5-2005

[Exhibit A]

MAINE RX PROGRAM REBATE AGREEMENT

BETWEEN

THE COMMISSIONER OF THE DEPARTMENT OF HUMAN SERVICES OF THE STATEOF MAINE

AND

THE MANUFACTURER IDENTIFIED IN SECTION VIII

OF THIS AGREEMENT

(Hereinafter referred to as the "Manufacturer")

The Commissioner, on behalf of the State of Maine, and the Manufacturer, on its own behalf for the purposes of complying with Public Law 1999, chapter 786, hereby agree to the following:

I. DEFINITIONS

The terms defined in this section will, for the purposes of this Agreement, have the meanings specified herein:

(a) "*AVERAGE WHOLESALE PRICE*" means the Wholesale Price charged on a specific commodity that is assigned by the drug Manufacturer and is listed in a nationally recognized drug-pricing file.

(b) "*CALENDAR QUARTER*" means four times a year. Specifically the first Calendar Quarter will be from January 1, 2001 — March 31, 2001. Each successive three-month period shall be a Calendar Quarter.

(c) "*COMMISSIONER*" means the Commissioner of the Department of Human Services.

(d) "*DEPARTMENT*" means the Department of Human Services.

(e) "*MANUFACTURER*" means the entity holding legal title or possession of the National Drug Code (NDC) for the Prescription Drug.

(f) "*NATIONAL DRUG CODE* (NDC)" is the identifying drug number maintained by the Food and Drug Administration (FDA). For the purposes of this Agreement, the complete 11-digit NDC will be used including the labeler code (which is assigned by the FDA and identifies the establishment), product code (which identifies the specific product or -formulation), and package size code to identify a prescription drug.

(g) "*NET SALES*" means Calendar Quarter gross sales revenue less cash discounts allowed and all other price reductions which reduce the actual price paid; and as discussed under the definition of WP.

(h) "*PRESCRIPTION DRUG*" means (1) legend drugs, defined as drugs carrying the statement "Caution: Federal Law Prohibits Dispensing Without A Prescription" and (2) any other drugs which by State law or regulation require the prescription of a licensed practitioner for dispensing. For purposes of this Agreement, all Prescription Drugs must be identified by the Manufacturer's labeler code segment of the National Drug Code (NDC).

(i) "*QUALIFIED RESIDENT*" means a resident of the State who has obtained from the Department a Maine Rx enrollment card.

(j) "*REBATE AMOUNT*" means the Medicaid Rebate amount.

(k) "*REBATE PAYMENT*" means, with respect to the Manufacturer's Prescription Drugs, the Calendar Quarter payment by the Manufacturer to the State of Maine which shall be the sum of the Rebates of each prescription drug (computed for each dosage form and strength of each Prescription Drug) calculated as follows:

(1) The total number of Units paid under the Maine Rx Program for qualified residents during the Calendar Quarter multiplied by the Rebate amount per Unit.

(2) Effective January 1, 2001, a percentage equal to the Medicaid Rebate percentage to the State of Maine in effect for the corresponding time period.

(l) "*UNIT*" means drug Unit in the lowest identifiable amount (i.e. tablet or capsule for solid dosage forms, milliliter for liquid forms, gram for ointments or creams). The Manufacturer will specify the Unit for each dosage form and strength of each Prescription Drug in accordance with instructions developed by the Health Care Financing Administration for purposes of the Federal Medicaid Rebate program under Section 1927 of the Social Security Act.

(m) "*UTILIZATION DATA*" means the information regarding the total number of Units of each dosage form and strength of the Manufacturer's Prescription Drugs paid during the Calendar Quarter under the Program. Drugs dispensed prior to January 1, 2001 are excluded. The Utilization Data includes: (1) 11-digit NDC, including package size code; (2) product name; (3) quantity of Units paid during the Calendar Quarter by 11-digit NDC; (4) total number of prescriptions paid during the Calendar Quarter by 11-digit NDC; and (5) total dollar amount paid during the Calendar Quarter by 11-digit NDC.

(n) "*WHOLESALE PRICE* (WP)" means, with respect to a Prescription Drug of the Manufacturer for a Calendar Quarter the average price paid by Wholesalers in the United States to the Manufacturer, for ultimate distribution to the retail pharmacy class of trade (excluding direct sales to hospitals, health maintenance organizations and to Wholesalers where the drug is relabeled under that distributor's national drug code). WP includes cash discounts allowed and all other price reductions, which reduce the actual price paid. It is calculated as a weighted average of prices for a Manufacturer's package sizes for each Prescription Drug by the Manufacturer during that Calendar Quarter. Specifically it is calculated as Net Sales divided by number of Units sold, excluding drugs or any other items given away but not contingent on any purchase requirements. For bundled sales, the allocation of the discount is made proportionately to the dollar value of the Units of each drug sold under the bundled arrangement. The V/P for a Calendar Quarter must be adjusted by the Manufacturer if cumulative discounts or other arrangements subsequently adjusted the prices actually realized.

(o) "*WHOLESALER*" means any entity (including a pharmacy or chain of pharmacies) to which the Manufacturer sells the Prescription Drug, but that does not re-label or repackage the Prescription Drug.

II. MANUFACTURER'S RESPONSIBILITIES

The Manufacturer agrees to the following:

(a) To calculate and to make a Rebate Payment each Calendar Quarter to the State of Maine for the Manufacturer's Prescription Drugs paid for by the Department pursuant to the Maine Rx Program during a Calendar Quarter under the Maine Rx Program as follows:

Manufacturer's first rebate payment for the Calendar Quarter January 1, 2001 through March 31, 2001 shall be due September 30, 2001, or 30 days after receipt of utilization data pursuant to Section III (a) of this Agreement, whichever is later.

All subsequent Rebate payments will be made by the Manufacturer to the State of Maine within 30 days of the close of each Calendar Quarter, or within 30 days upon receipt of the Utilization. Data pursuant to Section III (a) of this Agreement, whichever is later. Simultaneously, with each Rebate Payment, the Manufacturer will provide the Department with the Manufacturer's most recent price catalog, unless no price changes were made from the previous Calendar Quarter.

(b) To continue to make a Rebate Payment to the State of Maine on all of its Prescription Drugs as defined in this Agreement so long as this Agreement, or a successor Agreement, is in force and as long as such Prescription Drugs are dispensed under the Manufacturer's NDC. If there are no sales by the Manufacturer during a Calendar Quarter the WP used for the most recent Calendar Quarter in which sales occurred will continue to be used in calculating Rebates.

(c) The Manufacturer will be responsible for Rebates on claims for prescription drugs that were dispensed within one year of the date that the claim was paid by the Department.

(d) The Manufacturer agrees to maintain all books, documents, papers, accounting records, and any other evidence pertaining to this Agreement and make such material available at its offices during normal business hours and shall send copies of such material to the Department upon the request of the Department during the period of this Agreement and for a period of two years after the termination of this Agreement. The

Manufacturer shall allow inspection of pertinent documents by the Department or any authorized representative of the State of Maine, and shall furnish copies thereof, if requested.

III. COMMISSIONER'S RIGHTS AND RESPONSIBILITIES

(a) The Department, on behalf of the Commissioner, shall send the Utilization Data as defined in this Agreement, to the Manufacturer, by certified mail, return receipt requested, within 60 days following the last day of each Calendar Quarter for qualified residents. The Commissioner, through the Department, shall maintain electronic claims records for the most recent four Calendar Quarters that will permit the Manufacturer to verify through an audit process The Utilization Data provided by the Department.

(b) The Department shall conduct audits, as it deems necessary to verify rebate calculation and payment.

IV. DISPUTE RESOLUTION FOR DISCREPANCIES IN REBATE AMOUNTS

Discrepancies in Rebate amounts must be resolved using the following process:

(a) If there is a discrepancy in the Manufacturer's or labeler's favor between the amount claimed by a pharmacy and the amount rebated by the Manufacturer or labeler, the Department, at the Department's expense, may hire a mutually agreed-upon auditor. If a discrepancy still exists following the audit, the Manufacturer or labeler shall justify the reason for the discrepancy or make payment to the Department for any additional amount due.

(b) If there is a discrepancy against the interest of the Manufacturer or labeler in the information provided by the Department to the Manufacturer or labeler regarding

the Manufacturer's or labeler's Rebate, the Manufacturer or labeler, at the Manufacturer's or labeler's expense, may hire a mutually agreed-upon independent auditor to verify the accuracy of the data supplied to the Department. If a discrepancy still exists following the audit, the Department shall justify the reason for the discrepancy or refund to the Manufacturer any excess payment made by the Manufacturer or labeler.

(c) Following the procedures established in paragraph a or b, either the Department or the Manufacturer or labeler may request a hearing before the Department of Human Services Administrative Hearings Unit. Supporting documentation must accompany the request for a hearing.

(d) The Manufacturer further agrees that the sole and exclusive means for the presentation of any legal claim against the State arising out of this Agreement shall be in accordance with 5 MRSA section 11001. The Manufacturer further covenants not to initiate legal proceedings in any State or Federal court in addition to, or in lieu of, proceedings under section 11001. This Agreement shall be governed in all respects by the laws, statutes, and regulations of the United States of America and of the State of Maine. The Manufacturer consents to personal jurisdiction in the State of Maine.

(e) Nothing herein shall be construed or interpreted as limiting or otherwise affecting the Department's ability to pursue its rights arising out of the terms and conditions of the Agreement in the event that a dispute between the parties is not otherwise resolved.

V. CONFIDENTIALITY PROVISIONS

(a) Commercial or financial information disclosed by the Manufacturer in connection with this Agreement is confidential information, and will not be disclosed by the Commissioner or the Department (including any

auditors or agents thereof) in a form which discloses the identity of a specific Manufacturer or Wholesaler, prices charged for drugs by such Manufacturer or Wholesaler, in accordance with 42 U.S.C. § 1396r-8(b)(3)(D), 22 M.R.S.A. § 402(3) and Maine Rules of Evidence, Rule 507.

(b) The Manufacturer will guarantee the protection and confidentiality of the Utilization Date, including the proper care, custody, use and preservation of records, papers, files, communications of the Department and any other information that may reveal information related to the Utilization Data. If the Manufacturer audits this information or receives further information on such data, that information shall also be held confidential. The Manufacturer shall have the right to disclose Utilization Data to auditors who agree to keep such information confidential.

(c) Notwithstanding the non-renewal or termination of the Agreement for any reason, the confidentiality provisions will remain in full force and effect.

VI. TERMINATION

(a) Unless otherwise terminated by either party pursuant to the terms of this Agreement, the Agreement shall be effective for an indefinite period beginning on January 1, 2001.

(b) The Manufacturer may terminate the Agreement for any reason, and such termination shall become effective the first day of the first Calendar Quarter period beginning sixty (60) days after the Manufacturer gives written notice requesting termination.

(c) The Commissioner may terminate the Agreement for any reason, upon sixty- (60) days prior written notice to the Manufacturer.

(d) The termination of this Agreement by either party will not affect any Rebate payments due to the State of Maine.

(e) In the event that any element of this Agreement is affected by a legislative amendment, including, but not limited to the percentage amount of Rebate required, such amended or revised provisions shall be incorporated by reference within this Agreement and shall supersede any of the conflicting provisions of this Agreement. If either party is unwilling to accept such a change in terms, this Agreement may be terminated pursuant to the terms set out in subsections (a) through (d) above.

VII. GENERAL PROVISIONS

(a) Any notice required to be given pursuant to the terms and provisions of this Agreement will be sent in writing.

Notice to the Commissioner will be sent to:

Maine Rx Program
Director of Pharmacy Programs
Bureau of Medical Services, 3rd Floor
11 State House Station
Augusta, ME 04333-0011

Notice to the Manufacturer will be sent to the address provided to the Department by the Manufacturer.

(b) In the event of a transfer of ownership of the Manufacturer, this Agreement is automatically assigned to the new owner subject to the conditions specified in this Agreement.

(c) Nothing in this Agreement will be construed to require or authorize the commission of any act contrary to law. If any provision of the Agreement is found to be invalid by a court of law, this Agreement will be construed in all respects as if any invalid or unenforceable provision

were eliminated, without any effect on any other provision.

(d) Nothing in this Agreement shall be construed as a waiver or relinquishment of any legal rights of the Manufacturer or the Commissioner under the Constitution, the Social Security Act, other Federal laws or State laws.

(e) The terms "Department: and "Manufacturer" incorporate any contractors or agents thereof, which fulfill responsibilities pursuant to this Agreement unless specifically provided for in the Rebate Agreement.

(f) This Agreement will not be altered except by an amendment in writing signed by both parties and except as indicated in subsection VI (e). No person is authorized to alter or vary the terms unless the alteration appears by way of a written amendment, signed by a duly appointed representative of the Manufacturer, and the Commissioner, and approved by the Office of the Attorney General.

(g) In the event that a due date falls on a weekend, or a Federal or State holiday, the report or other item will be due on the first business day following that weekend or holiday.

VIII. MANUFACTURER'S ACCEPTANCE

I, _____ hereby agree to the terms
(Name of Authorized Representative)
of this Agreement for the following Manufacturer(s) and labeler(s):

_____ _____
(Labeler Name) (Code)

_____ _____
(Labeler Name) (Code)

_____ _____
(Labeler Name) (Code)

_____ _____
(Labeler Name) (Code)

_____ _____
(Signature) (Title)

Date: _____

[Exhibit B]

Maine Rx Program
Draft Proposed Rule for Prior Authorization Provision
9/00

"Drugs of non-participating drug manufacturers shall be reviewed by the Department as to the clinical appropriateness of prior authorization for those drugs. Recommendations to prior authorize any of those drugs shall be referred to the Medicaid Drug Utilization Committee, for a final determination of whether those drugs should be prior authorized, in accordance with federal and state law. In all instances, Medicaid recipients shall be assured access to all medically necessary outpatient drugs."

Maine Medical Assistance Manual, Section 80 (Pharmacy Services)
Draft Proposed Rule for Prior Authorization Provision
9/00

Amend Rule 80.01-7 (new words are underlined).

"Drug Utilization Review Committee means an advisory committee to the Medicaid Program, comprised of physicians and pharmacists, who are licensed to prescribe or dispense medications in Maine."

Propose New Rule:

"The Drug Utilization Review Committee shall consider and make the final determination regarding the clinical appropriateness of all prior authorization recommendations, including those concerning drug manufacturers who do not participate in the Maine Rx Program. In all instances, Medicaid recipients shall be assured access to all medically necessary outpatient drugs."

[Exhibit C]

Medicaid Outpatient Prescription Drug Spending

	SFY 97	SFY 98	Chg	SFY 99	Chg
Gross Expenditures	$98,964,628	$109,697,688	10.8%	$135,493,928	23.5%
Drug Rebates	-$17,206,484	-$20,206,046	17.4%	-$27,957,863	38.4%
Net Expenditures	$81,758,144	$89,491,642	9.5%	$107,536,065	20.2%
Drug Rebate Percentage	17.4%	18.4%		20.6%	
Number of Drug Recipients	141,220	144,205	2.1%	148,654	3.1%
Gross Exp Per Recipient	$700.78	$760.71	8.6%	$911.47	19.8%
Net Exp Per Recipient	$578.94	$620.59	7.2%	$723.40	16.6%
Number of Prescriptions	2,793,666	2,870,422	2.7%	3,114,155	8.5%
Prescriptions per Recipient	19.8	19.9	0.6%	20.9	5.2%
Expenditures per Prescription	$35.42	$38.22	7.9%	$43.51	13.8%

November 29, 1999, Christopher Nolan, Bureau of Medical Services, Department of Human Services

UNITED STATES DISTRICT COURT
DISTRICT OF MAINE

PHARMACEUTICAL RESEARCH, of AMERICA — CIVIL ACTION

Plaintiff — Docket No. 00-157 B-H

v

COMMISSIONER, Maine Dept of Human Services

Defendant

Transcript of Proceedings

Hearing on Preliminary Injunction before HON. D. BROCK HORNBY in the United States District Court, Edward T. Gignoux Courthouse, 156 Federal Street, Portland, Maine, on the 19th day of October 2000 as follows:

Appearances:

For the Plaintiff: Bruce C. Gerrity, Esq.
Preti, Flaherty, Beliveau
Allen S. Rugg, Esq
and
Marinn F. Carlson, Esq.
Powell, Goldstein, Frazer & Murphy

For the Defendant: Andrew S. Hagler, Esq.
Attorney General's Office
John Brautigam, Esq.
Cabanne Howard, Esq.

Pauline D. Terry, RPR, CM
Official Court Reporter

Transcript recorded by mechanical stenography, transcript produced by computer aided transcript.

(Transcript of hearing on motion for preliminary injunction before HON. D. BROCK HORNBY in the United States District Court, Edward T. Gignoux U.S. Courthouse, Portland, Maine, on the 19th day of October 2000 beginning at 9:00 AM as follows:)

THE COURT: Good morning. (Counsel responded).

The matter on for hearing is civil number 00-157 P-H, Pharmaceutical Research Manufacturers of America versus the Commissioner of Maine Department Human Services et al. And the matter is on this morning for a hearing on the plaintiff's motion for preliminary injunction. I know there's a wide degree of interest in this case and let me, therefore, just summarize a couple of things that the lawyers already know.

I did hold a telephone conference with the lawyers two days ago, I guess it was, counsel, at my request. The reason for the telephone conference is that the preliminary injunction issue is going based upon affidavits and arguments presented in writing, and the arguments made here this morning. I was inquiring of the lawyers whether it was possible to consolidate into one hearing all of the factual issues that might be present in the lawsuit. That is something that a Federal Court can do under Rule 65, under appropriate circumstances.

As a result of the telephone conference, however, I concluded that it would be premature to do that and so the hearing is going forward on the original premise, which is to say my decision will be based upon the written submissions consistent with the legal arguments, affidavits, legislative materials and things of that sort.

I will also say at the outset that I will not decide the case today. I will hear the arguments. This is a complex matter. I will issue a written decision after I've had the opportunity to digest things I hear this morning. I have read everything submitted. By the way, counsel, I received everything that

each of you submitted in the last day, both the state and the plaintiff, proposed and legislative debate.

The final thing I will say before I hear argument, just an explanation of a couple of terms for the benefit of people in the audience.

I think everyone knows that there are constitutional issues being raised here, and under the federal constitution there is a provision called the Interstate Commerce clause that in Article 1 section 8 of the constitution says, Congress shall have power to regulate commerce with foreign nations, and among the several States, and with the Indian Tribes.

There is a doctrine, and you will probably hear the lawyers refer to it, this is why I want to mention it, called the Dormant Congress Clause. This is a term that only lawyers would understand, that's why I mention it. The theory is, the doctrine is even when Congress does not actually exercise its power to regulate commerce, under Article 1 section 8, that there is a dormant power there which, in some circumstances, even in the absence of regulation, a state cannot threaten that theory, and you will probably hear reference to it in discussion.

The other provision that is at issue is Article 6 of the Constitution that says: This Constitution, and the LAWS of the United States which shall be made in Pursuance thereof, and all Treaties made, or which shall be made, under the authority of the United States, shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any State to the Contrary notwithstanding.

That is often called the Supremacy Clause. And there will be argument here today as to whether the Supremacy Clause has any effect on any law.

I just announced that for the benefit of the reporters that might not understand the language being used.

Mr. Gerrity, I will ask you to introduce your co-counsel.

MR. GERRITY: Thank you, your Honor. If I could, I would introduce the Court to Allen Rugg of Powell, Goldstein, Frazier & Murphy. Mr. Rugg will be presenting the oral argument today. With him is Marin Carlson, also of his firm and Daniel Price, who is here as well.

THE COURT: Thank you. Before you start, Mr. Hagler, do you want to introduce your group?

MR. HAGLER: Yes, thank you, your Honor. With me from the attorney general's office is John Brautigam, and also Cab Howard, whom the state is pleased to have join us in these proceedings. I will be arguing the case your Honor.

THE COURT: Thank you. Mr. Rugg, I'll hear you.

MR. RUGG: Thank you very much, your Honor. It is an honor to appear before the Court and we appreciate the Court's scheduling this argument on Pharmaceutical's motion for Preliminary Injunction.

As the Court is aware, the relief that PhRMA is seeking is an immediate Preliminary Injunction restraining the implementation and the enforcement of the Maine Rx program and the related antiprofiteering section of the statute. It is our contention that those statutes violate the constitution with regard to the Commerce Clause, and with regard to the sanction of requiring prior authorization in the unrelated Maine Medicaid program that the statute violates the Supremacy Clause.

Your Honor, the member companies of PhRMA are at immediate risk and will face irreparable injury absent relief from this court. The state is presently implementing this statute. The implementation began on August 2nd, a week before the effective date of the statute.

Presently our member companies have a deadline to respond to the Commissioner's request that they execute rebate agreements by November 1st.

Interestingly, I read in the Wall Street Journal two days ago that Mr. Concannon has announced that after November 1st he intends to take out newspaper ads publicizing the names of companies that have elected not to execute the agreements. We understand that at that time, after November 1st, the companies will be at risk to have their prescription drugs that are distributed to Maine Medicaid recipients subject for the first time to prior authorization.

The record in this case is absolutely unchallenged as to the impact of such prior authorization, on the manufacturers. There is potentially a dispute in this case as to the impact on Medicaid recipients, and I will certainly address that. But for purposes of evaluating the standards for the issuance of a Preliminary Injunction, there is no question that prior authorization will work an immediate irreparable injury to the companies, and I specifically invite the Court's attention to the unchallenged declaration of Dr. Moules from Smith/Kline Beecham.

Let me pause just a moment here. I don't want to misspeak but there are portions of the Moules declaration that are subject to disagreement. When I say that it is undisputed, I'm addressing the portion of his declaration that describes the impact on companies when prior authorization is imposed, and specifically historical data of the impact on market share and sales of four specific drugs.

So, the impact is immediate and it should come as no surprise because when this statute was considered in the legislature, Senator Pingree, and in this legislative history that we just submitted to the Court which just became available to us, Senator Pingree stated if companies do not participate in this program, they will not be able to participate in Medicaid. And that the full, all the tools of the statute will be brought to

bear on companies to compel them to participate in this program.

Commissioner Concannon followed up on that, as I say, a week before the statute even became effective by requesting that the parties immediately execute rebate agreements.

Your Honor, if I may, I would like to address the likelihood of success on the constitutional challenges to the statute. With regard to the Maine Rx rebate, our principal argument, your Honor, is that Maine seeks to regulate out-of-state transactions. I would urge the Court to consider the declaration of Judith Tempel, who is Manager of Distribution Operations of Eli Lilly, that declaration is also unchallenged. Ms. Tempel reports that on August 4th, Ely Lilly in its headquarters in Indianapolis received a letter from Commissioner Concannon. The letter said, "Sign the enclosed rebate agreement. And if you don't, be aware of the antiprofiteering sections of the statute, the prior authorization sanction."

So, when you turn, and this is an exhibit to Ms. Tempel's declaration. When you turn to the proposed rebate agreement, it makes very clear that the state seeks to regulate and receive a payment from Eli Lilly in Indianapolis, Indiana for each prescription pill of Eli Lilly that crosses the counter of a pharmacist here in Maine. That is the only construction possible of the proposed rebate agreement.

I would ask the Court to then consider Ms. Tempel's declaration. Eli Lilly does not manufacture its drugs here in Maine.

It sells its drugs through warehouses in Connecticut, Indiana, and California.

It sells those drugs by distributors and manufacturers coming to Eli Lilly, negotiating arms length purchases of those drugs, which are not identified for shipment to any location in the United States. Pursuant to the agreement

between Lilly and the distributors, title passes at the warehouses, all outside of the State of Maine. And then, finally, the purchaser makes payment to Eli Lilly in Pittsburgh Pennsylvania. What is conspicuous is the absence of any act in this process that occurs in the State of Maine.

The distributors then selling, but the purpose and the effect of the rebate agreement is to change those transactions that occur in Pennsylvania, Indiana and California, changing the economics of Lilly's sales transactions, and taking money out of that transaction and moving it to Maine.

Your Honor, please, we submit that that evidence is unchallenged, uncontroverted and for very good reason.

There is one distributor that does business here in Maine, Bindery Western. A number of our member companies do some business with them, but the vast majority of the prescription medications that are sold here in Maine come to Maine through third-party distributor or wholesale. And we submit to the Court that we believe that's why this portion of our case is uncontroverted by the state. The state realizes that is the true factual record. And then we presume, we will argue to the Court that nevertheless, even though these transactions occur out of state, this statute, for some reason does not directly regulate those transactions.

THE COURT: I'm not sure what you're saying here. Are you saying that it can't apply to Bindery, or whatever that is, but not the others?

MR. RUGG: We think it could. We are submitting to the Court with regard to extraterritoriality argument, we would ask the Court to determine that to the extent that sales occur and are consummated outside the State of Maine, the statute cannot constitutionally regulate those transactions.

THE COURT: Let me press you on that language, outside the State of Maine, you told me, as you characterize it, in the vast majority of cases it's a transaction between a seller and a

distributor both of whom are located outside of Maine and title passes outside of Maine?

MR. RUGG: Yes sir.

THE COURT: You say there are a small portion of cases where a distributor is in Maine, and are you saying that title passes there in Maine? Outside of Maine? Does it matter? What is your contention there?

MR. RUGG: What we are contending is to the extent the transaction is concluded in Maine, if title transfers and the Bindering transaction, if you will, that occurs in Maine, we respectfully submit that our extraterritoriality argument would not attach to those transactions.

Of course, we persist in our contention that the benchmarking problems under the Commerce Clause would still apply to those transactions.

Your Honor, with regard to this extraterritoriality issue, we submit that the legal authorities are clear, that Maine simply has no authority to go beyond its borders to exercise regulation of transactions in other states.

If your Honor please, I would like to turn to the benchmarking argument.

THE COURT: Go ahead.

MR. RUGG: The statute—let me back up. In August when this statute was considered, the clear argument before the senate was the manufacturers would be required to initially provide the Medicaid rebate to Maine residents. That's the force also of Commissioner Concannon' s letter of August 2nd.

The Medicaid rebate amount, under the Medicaid program, is provided by statute. And in general terms, it is the greater of 15.1 percent less than the average manufacturer's price, or the spread between the average manufacturer's price and the manufacturer's best commercial price.

Now, understandably there is a lot of federal regulation but that's the basic formula. What is critical for today's purposes, that is not a statutory number, it is a statutory formula, that is applied on an ongoing basis and is driven by economic market transactions all over the United States. So, if a manufacturer who is participating in Medicaid decides to offer a best price to a commercial customer in Colorado, that affects the Medicaid rebate, Medicaid is a national consensual program, manufacturers make a decision whether they want to participate in Maine Medicaid or whether they want to participate in Medicaid nationwide.

So manufacturers having made that decision understand that market transactions that they enter into affects the Medicaid price.

This statute seeks to exploit that Medicaid calculation for purposes totally unrelated to Medicaid, for the sole purpose of driving down prices of prescription drugs for citizens of Maine. There is no Medicaid interest here, it is simply, you are borrowing the formula and applying it in this state's statute.

What's crucial for the benchmarking analysis is that with this statute, prices in Maine are linked or indexed to prices that are made in market transactions entirely outside of Maine. And we urge the Court to consider the application of *Sealig and Healy* because we think that this statute in effect is quite analogous to the price affirmation statute, for example, that was the subject of the *HEALY* case.

Your Honor, I'd like to turn to the consideration of the sanction of prior authorization.

When we had our telephone conference hearing two days ago we had some discussion of whether there would be issues of fact related to this issue. And our representations to the Court were that we think this is really a legal question. And the legal question, your Honor, I alluded to it earlier, is whether without violating the Supremacy Clause of the

United States Constitution can Maine borrow or take the Medicaid formula and apply it in this case. And if it does, is the vehicle for driving it, namely prior authorization in unrelated programs, consistent with the Supremacy Clause.

THE COURT: I take it by the thrust of your argument that you are agreeing that the publicity requirement alone would not be a sanction that violates the Supremacy Clause.

MR. RUGG: Your Honor, that is correct, we do not contend that that is a violation of the Supremacy Clause.

THE COURT: Or even the Commerce Clause?

MR. RUGG: No, but we think—I'm sorry, to be clear, I agree with the Court. But we think the publicity sanction is important for applying the Preliminary Injunction standard.

THE COURT: I understand.

MR. RUGG: Okay. Your Honor, the nub of the Supremacy argument is that Medicaid prior authorization becomes a tool or a weapon to coerce participation in the Maine program. There can be no mistake that the state recognizes this. When Senator Pingree states, if in fact the manufacturers choose not to cooperate, we will use all the tools available to us here in the State. We will require their participation in this program if they want to participate in the Medicaid program. If they want to participate in the National Medicaid Program, they have to participate in this Maine program. That is what the Senator said, and that is clearly the purpose of the prior authorization sanction in this statute.

And today as we sit here, that is the weapon that is waiving around.

It's the weapon that Commissioner Concannon built August 2 letter.

It is the subject, when he is interviewed in the press, it's the weapon that he invokes.

THE COURT: Whether Senator Pingree said that or not, there is nothing in the statute that takes the manufacturer out of the Medicaid, it is limited to prior authorization if they choose not to comply with the Maine Rx.

MR. RUGG: The statute simply provides that it is not discretionary, that the state shall prior authorize the manufacturer's drugs if they do not participate.

THE COURT: So the question is the bite of that the state

into his provision as—

MR. RUGG: Right. Now, I'm concerned that since, at a very high level we are talking about prescription drugs. We could jump to the conclusion that prior authorization in Medicaid is really quite consistent with prior authorization under the Maine statute.

If your Honor please, let's imagine it's January, next January, and let's assume that certain manufacturers have not participated, for the first time, even though Maine has participated in Medicaid for many years, and has utilized prior authorization for Medicaid purposes, by the force of this statute, manufacturer's drugs are prior authorized for the first time. What has changed?

Has the clinical research changed?

Has the medical literature changed?

Has the assessment of patient need changed?

What has changed is that this statute has become effective and the weapon, the coercive weapon is being brought to bear.

Now, I would like to suggest one other possible way of looking at this. Let's suppose that this statute says that the manufacturer shall make rebate payments, and that the state shall use these rebate payments for elementary school education or for building roads, or dredging the harbor. And

the weapon to coerce this participation is prior submitted authorization.

I think under that scenario there would be no debate as to whether the prior authorization under the Medicaid statute was being used improperly for an unrelated state purpose, and the result being an obstacle and a burden to the realization of the goals of the federal program.

Finally, on this point, we note the declaration by Maine.

The board that will be making these decisions has in the past been making Medicaid decisions. The resources and the personnel who have traditionally implemented Medicaid are suddenly being charged with the responsibility of implementing a very narrow specific state statute.

THE COURT: Let's be precise on the Supremacy—

MR. RUGG: Yes sir.

THE COURT: —argument. Congress has not specifically said this is prohibited, has it?

MR. RUGG: Has not.

THE COURT: So to respond to the attorney general's argument that there are two requirements for prior authorization—

MR. RUGG: Correct.

THE COURT: —being met.

MR. RUGG: That is correct. We do not base this argument on the provision of the Medicaid statute.

THE COURT: What do I have by way of a Chevron type analysis as to whether the Secretary of Health Human Services, or the Health Care Financial Administration or anyone else has given any kind of interpretation?

MR. RUGG: Draft regulations are in the process.

THE COURT: You are referring to state regulations; are you not?

MR. RUGG: Federal.

THE COURT: Tell me about that.

MR. RUGG: I want to be precise, your Honor. My recollection is that the proposed regulations would limit the use of prior authorization for implementation of the Federal Medicaid program but to be absolutely precise, your Honor, I would like to have the ability to follow-up on that.

THE COURT: Actually if you can in writing give me a federal register or citation.

MR. RUGG: We would be happy to.

If I may follow up on the Court's observation, recognizing that the only language in the statute dealing with prior authorization imposes conditions of the use of prior authorization that are of course consistent with its operation of the Medicaid program, I believe its availability of drugs on a 24-hour basis.

The statute does not address the utilization of prior authorization to enforce a totally unrelated statute. And we would submit to the Court perhaps the reason for that is that it would never occur to Congress that a Medicaid statute would be used as the coercive enforcement tool in a totally unrelated purpose. Take my example, if you will, of a program to fund education here in Maine, or roads here in Maine, would you expect the statute to say Medicaid prior authorization cannot be used as a vehicle to enforce contributions to the—fund in Maine. I think the only reason this becomes a narrower issue is, as I said earlier, perhaps at one level one could try to reconcile the federal Medicaid program and the state program as being a consistent common program but these are different populations, different agendas. And what's crucial is the Medicaid program is indeed a national program.

Finally, your Honor, with regard to the likelihood of success on the merits, I'd like to address the antiprofiteering portion of the statute.

THE COURT: Are you going to address the market participation?

MR. RUGG: I would be happy to. Let me do that right now. Our view is that the State of Maine is not participating in this program in a proprietary sense as either a purchaser or seller of drugs. This is classical regulation. The rebate agreement that you saw, Commissioner Concannon sent to Eli Lilly, simply regulates the transaction and the money that is generated from the transaction is then distributed. This is not a state acting in a market place capacity of buying drugs.

Now, we think it could be argued that the state functions as a market participant in the Medicaid program.

We would submit to the Court that that is an entirely different market, different program. We would cite to the Court the Supreme Court case that stands for the proposition that a state may not leverage its power in one market to regulate another one.

THE COURT: What is the case, the Alaska case?

MR. RUGG: Yes sir.

MR. RUGG: With regard to antiprofiteering, clearly today, or maybe speaking more precisely, November 2nd, the companies are at risk to be prosecuted. And the prosecution, it sounds like, would be founded upon their failure to submit to the regulation of the out—of—state transactions in the form of entering into rebate agreements. It's a real risk and the issue is precisely the issue we discussed earlier, the extraterritoriality element.

The failure to submit to the regulation of these foreign transaction exposes companies to that risk.

THE COURT: If it is extraterritoriality, again this is with respect to your argument of what you call the vast majority of the cases but not cases of a distributor in Maine?

MR. RUGG: Right.

THE COURT: Go ahead.

MR. RUGG: The statute makes findings. The state, the legislature has already determined that the manufacturers are in violation of this statute by making statutory findings that the companies charge excessive prices and realize excessive profits. So we have a statute that has made the finding.

We have a statute that imposes a standard of what is profiteering, and we have a statute that provides for immediate power to enforce it through prosecution. Additionally, we are at risk under the Unfair Trade Practices portion of the statute to private litigation over this issue.

Your Honor, I believe I have addressed the likelihood of success on the merits of the constitutional arguments. I would submit to the Court, as I indicated to you two days ago over the telephone, these issues can be decided legally. The facts are not in dispute. The extraterritoriality transactions, the rebate agreement that is indexed to Medicaid, the linkage to the other state transactions, the fact that the companies are compelled to enter into those agreements is not reasonably in dispute. So we submit to the Court that these issues are ripe for decision.

I have already addressed the hardship on the companies that would require the issuance of immediate injunction.

I would like to address the state's interest in avoiding an injunction today.

If you will, the status quo stands to be altered by the effectiveness and the implementation of the statute. There has never been prior authorization of Medicaid drugs for

other state purposes. There has never been the regulation of out—of—state transactions.

There has never been the overt public threat by a public official to run newspaper ads damaging these companies. None of that has occurred historically, it is prospective. The status quo will be preserved by this Court staying the implementation of this statute while the Court has the opportunity to decide these important constitutional issues.

The state cannot in good conscience be heard to argue that it has an interest in the enforcement of a non-constitutional statute.

And I would submit to the Court that we have not heard that from opposing counsel. We don't expect Mr. Hagler will argue to the Court this state has an interest in enforcing an unconstitutional argument. We think he will say the statute is constitutional.

So the real issue here is who will prevail at the end of the day on these critical constitutional issues on whether this statute is constitutional. We submit to the Court that the prudent course is to stay implementation and allow the judicial process to work.

Finally, with regard to the last prong, PUBLIC INTEREST, I don't think I need to belabor that because once again the public in Maine has an interest in its statutes complying with the federal constitution.

We all share that common interest, and that is the compeling public interest.

Your Honor, I would be happy to respond to any other questions the Court might have.

THE COURT: You have not addressed orally one argument that you addressed in writing concerning a third part of the statute which you characterized in writing as RETALIATION.

MR. RUGG: Yes, thank you, your Honor.

The statute, I would respectfully submit, is somewhat vague but we read that provision as saying the companies are compelled to do business in Maine. That if they are doing business in Maine, and because of the threat of this statute, they decided to reorder their business affairs to avoid the regulatory force of this statute, we believe they are at risk under the anti-retaliation provision of this statute. And if that's the case, we submit that it is unconstitutional for a state to enact a statute that compels companies based in Indianapolis Indiana to do business in Maine and to not leave Maine.

THE COURT: But at the moment that is a fairly abstract proposition, is it not, in the sense that I don't know what actions your companies might take to try to avoid Maine legislation. It is conceivable, is it not, that some of their activities might be subject to the statute and others might not? Isn't this a classic case of unripeness for a decision?

MR. RUGG: I understand the Court's concern but it seems that the Court could certainly render a limiting interpretation of the statute such as the Seventh Circuit in the K-S Pharmacy case.

One possible response is for the state to say, of course we don't construe this statute as mandating the continued presence of business operations in Maine. Of course we don't do that because that would be unconstitutional.

If the state does not take that position, we submit to the Court that it would be appropriate and right for the Court to render that type of decision.

Now, there may be further litigation in specific cases down the road that might move that line to apply to other transactions. But at this point we are simply talking about the fairly clear risk of, if a company responds to that statute and

changes its business transactions into another state, is it at risk?

THE COURT: All right, fine, let me find the think I have it.

MR. RUGG: The statutory provision, your Honor?

THE COURT: Yes, the language that refers to manufacturer or distributor or labeler that intentionally prevents limits or lessens or restricts the sale or distribution of prescription drugs in the state. Is that the one?

MR. RUGG: That's the one, your Honor.

THE COURT: All right, thank you, Mr. Rugg, I understand your argument.

MR. RUGG: Thank you very much, your Honor.

THE COURT: Mr. Hagler?

MR. HAGLER: Thank you, your Honor. It is both my duty and honor to argue in favor of this statute and that it is indeed constitutional.

The status quo, and that is what we are here today to decide, is whether the status quo should remain in pending litigation of the constitutionality of the statute, is not good enough. The status quo means that people will remain sick, and will remain unable to afford prescription drugs which they need.

The first test to determine is whether a Preliminary Injunction ought to issue ought to be a balance of the relative harms between the parties. And the state submits that requiring citizens to endure unaffordable drug prices, which is what the result of an injunction preventing implementation of this statute would be, outweighs the harms that are speculated to be the result of the statute by the plaintiffs.

We have cited studies in our papers, your Honor, which indicate that the price of 50 drugs most frequently used by the

elderly increased 4 times the rate of inflation in 1998, that the average price in Maine, the average retail price at the pharmacy for cash transactions in Maine of the 10 most prescribed drugs for the elderly were 86 percent higher at the pharmacy than the price for those same drugs that is charged to the federal government and to the drug companies' most favorite customers in Maine.

When one looks at the five most prescribed for the elderly, that is as high on average as 134 percent.

In the litigation of this case, the state will show that people are choosing not to fill prescriptions that their doctors write because they simply can't afford the price, that people are skipping dosage or splitting pills in a dangerous attempt to economize because they simply cannot afford the price. The public interest which provided the impetus for adopting this statute greatly outweighs the speculative effect on Interstate Commerce that the plaintiffs allege. For that reason we believe that the balance of harms way is in favor of denying the motion for injunction and also that because the state's interest so vastly weighs any speculative purpose on the part of the plaintiff, that the scrutiny on the issue of the likelihood of success on the merits of the case should be applied so that the plaintiffs are forced to prove a strong likelihood of success on the merits of the case. And we submit that this they have not done.

I was intending to address the Commerce Clause argument first, your Honor, but I would like, however, to take up the preemption argument because I think that I can illuminate some of the discussion regarding proposed rules by HCFA, the federal agency which regulates the federal aspects of Medicaid, and the use of a prior authorization in the Maine Rx statute as a mechanism for encouraging participation in that program by applying prior authorizations in the Medicaid program.

And I believe that I have a copy of the appropriate Federal Register and I would be happy with counsel's permission, and the Court's permission, to pass that up and to counsel.

THE COURT: Well you can do that. If you show it to him and he agrees that's fine.

MR. RUGG: Your Honor, may I have just a moment?

THE COURT: Of course.

MR. RUGG: Thank you, your Honor.

MR. RUGG: No objection.

THE COURT: Thank you.

THE COURT: Just so the record is clear, Mr. Hagler has handed me a portion of the Federal Register dated September 19, 1995, concerning proposed rules 42 CSR, 441 and 447. Go ahead.

MR. HAGLER: The federal Medicaid statute is vastly complicated, and as one can see by the number of pages that I have handed up to your Honor, some are proposed rules and comments and answers to comments which surround them. It is my understanding these rules have not been adopted. I will be referring to comments further along in my argument. It is important to recognize that the implementation of a prior authorization requirement in the Medicaid program for any particular drug is not a fait accompli as a result of the adoption of the Maine Rx program.

First, Medicaid establishes the right of the states to use prior authorizations in the Medicaid program. And what a prior authorization requirement is, with respect to a drug, is that a state is free to determine for any particular drug, that that drug should appear on what is called a prior authorization list. And what that means is that if a patient, entitled to receive Medicaid benefits, goes to their doctor, their doctor wishes to prescribe a particular drug, and if that drug appears on the list, then before Medicaid will reimburse the pharmacy

for filling that prescription, the doctor must speak with the state, and the doctor must speak with the state and have access to medical personnel to make the doctor's case that that drug is appropriate for that patient, that is appropriate for that patient because it won't counter act with another substance, another drug the patient might be taking. That it's the appropriate drug because there are no other alternatives which could help the patient with respect to the condition that they suffer, and perhaps even to explain to the state that other drugs were utilized to no effect and; therefore, this is the drug of last resort.

Medicaid requires that if a drug is placed on a prior authorization list, that there be a mechanism so that patients will be assured of getting that drug if they need it.

The Medicaid statutes can also be read such that the decision to place a particular drug on the prior authorization list, and the decision whether to prescribe it, must be governed by notions of medical necessity. But all that the Medicaid statute says about prior authorizations is that states may adopt that requirement in their Medicaid program. And then it says only two other things:

It says if you do have a prior authorization mechanism, there must be a provision for the phone to be answered when the doctor calls within 24 hours.

And there must also be a provision for dispensing on an emergency basis a 3 day suppliable drug which I believe is to cover instances in which the phone is not answered because of a holiday, and that is all the Medicaid statute speaks to.

Congress, therefore, has not affirmatively preempted in expressed language, the use of prior authorizations at all of events with respect to these two provisions. And, in fact, affirmatively granted to 'the states the right to engage in prior authorization.

Now, I would refer the Court and counsel to page 48473.

THE COURT: Go ahead.

MR. HAGLER: Of the federal register that I handed to the Court. And that is the area of the federal Register in which HCFA, the federal agency, is responding to concerns or questions that were received after proposing the rules. And I'm looking at the last column, the third column on the right, and towards the top of that column, the commentator is concerned about 3 things:

One is what if a state were to put on the prior authorization list all drugs of a particular manufacturer, or all drugs of all manufacturers, except the least expensive product in a therapeutic class.

Or—

And I'll skip to the third question. What if a state were to automatically place a prior authorization on the most expensive drug in a therapeutic class without regard to improved outcomes or reduction in total treatment cost associated with that more expensive drug therapy. And the answer of HCFA in construing Medicaid statute is clear, it is found further on down.

HCFA states: We believe that the state should be able to consider both clinical and economic criteria in their prior authorization programs as long as medically necessary drugs are not denied.

That would be okay.

The third question posed in the comments was:

It reads, the drugs if prior authorization—strike that, I'm not going to quote it. It asks—what if states try to get a better Medicaid rebate than the federal Medicaid rebate and used prior authorization, the threat of prior authorization of placing drugs on a prior authorization list, as the incentive to force drug companies to give that better Medicaid rate.

This appears to contemplate that it is possible for states to negotiate better Medicaid rebate for their Medicaid rebate than what the federal government negotiates for them and which otherwise applies across all the states.

This question suggests: What if a state were to say, and if you don't give us a better Medicaid rebate, we are going to consider using prior authorization.

And, again, HCFA says there is no problem with that.

They suggest that states can negotiate separate agreements for additional rebates as long as they comply with the requirements of the statute, and as long as the plan to consider prior authorization insures that patients will receive medically necessary drugs.

The states rules as proposed rules, and they have been proposed and published, as I understand, and we presented them in final form to the Court yesterday. And indeed they do differ in language, in slight variations in language from the form that they took at the time we wrote our briefs but the substance is the same. If a non-participating company, a company that refuses to enter into a Maine Rx rebate program, if they refuse to sign a rebate agreement and refuse to negotiate with the commissioner, the state's D U R committee (Drug Utilization Review Committee) can take off on a drug by drug basis, a decision tree of whether on a drug by drug basis, the drugs of those non-participating companies ought to be placed on that priorauthorization list.

THE COURT: Let me stop for a moment and have you elaborate on a couple of subjects. First of all help me with the Chevron analysis and what you have pointed me to in the Federal Register. You told me, I think, and Mr. Rugg told me of these proposed federal regulations have not been adopted. If that is so, do I have anything here that is authoritative in the Chevron sense on the Supremacy argument, and also can you tell me, do you know anything about why they have not been adopted, and what the status is?

My second question is going to be with respect to state regulations, let's leave it federal at the moment. Can you elaborate on that?

MR. HAGLER: I don't know the reason. I do not believe they were adopted because plaintiff's counsel cited to these in their papers as proposed, and I assume that is correct. And, again, of course these are statements of HCFA interpreting Congress' intent.

THE COURT: My question to you is: When they are still proposed and we have a response to comments but HCFA has not gone forward and adopted, do I have authoritative statements for Chevron purpose?

MR. HAGGLER: I don't know, your Honor, but I would be happy to brief that. I don't know the answer to that.

THE COURT: Let me turn you to the state regulation, your opponent's argument, I think I heard him say on the telephone, perhaps written papers, that the secretary can't rewrite the statute and that that is what he believes is happening here. Would you address that and explain to me what you mean by their decision tree approach as to whether or not an operating manufacturer will have its drugs automatically listed or not listed?

MR. HAGLER: Yes your Honor. First of all the statute states that the department shall adopt prior authorizations, as permitted by law, for companies that don't participate in the Maine Rx program. As permitted by law is the critical phrase and it's the phrase I believe the plaintiff's argument leaves out of the statute.

The commissioner and the department recognize that there is a constraint and it's expressed in HCFA's comments in the Federal Register to implementation of a prior approval, prior authorization process, and that constraint, aside from two examples that Congress put into the statute, is that in all event, or in any event patients entitled to Medicaid

reimbursement must receive drugs which are medically necessary. And the medically necessary determination comes about in two places, it comes about when the doctor calls the pharmacist or the pharmacist working for the state to request prior authorization. And there is always access ultimately to a physician who is employed by the State of Maine, who will make the medical necessity determination.

But it is also, as written in the rules, a guiding principle which the department will endeavor, has expressed an indication and will endeavor to consider, and to consider as the paramount factor in whether on a case by case basis any drug ought to be prior authorized.

THE COURT: Explain that to me. Suppose the XYZ pharmaceutical corporation manufacturer in New Jersey refuses to comply at all with the Maine Rx program and deadlines passes, are all its drugs then listed for prior authorization or are you telling me that there is then a further decision drug by drug of that company as to whether they will be listed or not?

MR. HAGLER: It is the latter.

THE COURT: So conceivably XYZ pharmaceutical of New Jersey, if they completely refuse to cooperate, that the state might conclude all of its drugs are so important that they are not on the prior authorizational list?

MR. HAGLER: That's correct, the hypothetical drug company could have a cure for aids and a cure for cancer that no other drug company has, and to place those drugs on the prior authorization list, because that company did not participate in the Maine Rx program, would have the result, would not be a decision consistent with medical necessity because any time a doctor wanted to prescribe that drug for cancer or HIV, the decision would be yes.

Now, I believe that the rules which affect this, I believe, are found in the pharmacy rules in section 80.05-3.

THE COURT: Say that again?

MR. HAGLER: The easier way, it's the thicker of the green packages and it's on page 8 with the numbers on the bottom, and then it's the second full paragraph on that page.

It reads: Drug Utilization Review.

THE COURT: Yes, I have it.

MR. HAGLER: It says: "The drugs of manufacturers that don't participate in the agreement shall be reviewed by the department as to the clinical appropriateness of prior authorization for those drugs under the Medicaid program.

Well, that implies that if you're going to make a clinical determination you have to do it on a drug by drug basis. Even further, the rule reads:

"Recommendations to prior authorize any of those drugs shall be referred to the Medicaid Drug Utilization Review Committee for a final determination of whether those drugs should be prior authorized in accordance with federal and state law. In all instances Medicaid recipients shall be assured access to medically necessary outpatient drug".

There's a similar provision in the Maine Rx rules regarding prior authorization. They are similar because they relate to each other.

THE COURT: I think you mentioned this to me on the telephone but tell me again. What is the ordinary amount of time under state necessary procedure law for public comment and—

MR. HAGLER: Ultimately I believe 40 days, 10 plus 30, and I believe, and I will correct myself after this hearing if I'm wrong but I believe the rules were published yesterday, meaning that notice went out in the paper yesterday and they were being sent to people who had requested them, and I have not calculated what the—

THE COURT: Let me take it one further step. If a broader reading of the statute were too broad and that this interpretation were necessary to preserve the statute on the face of the supremacy challenge, what do I do with the fact that these are still only proposed?

MR. HAGLER: The department didn't believe, and I hope I'm answering your question not with rhetoric, but the department didn't believe that "as permitted by law" in this area, as much as it is interfacing with Medicaid, could mean anything but a requirement that the decision to put a drug on a prior authorization list in Medicaid could be divorced of medical necessity. And so, notwithstanding that the rules are not adopted, I think that the rules in this respect or at least the spirit of these particular provisions is necessary.

THE COURT: I understand, thank you.

MR. HAGLER: Unless your Honor has anymore questions with respect to the preemption argument, turning back for a moment with respect to the Federal Register, the commentary, and this may go to the question that I was unable to answer. The commentary suggests that prior to the enactment of—no, strike that, I can't.

Turning to the Commerce Clause, and again it's important to recognize that in light of the strong state interest in adopting the statute, and the speculative nature of the harms alleged by the plaintiffs, they ought to have to prove that they are going to win almost to a high degree of certainty, likelihood should be in capitals and bold. But nonetheless we believe they have failed under the Commerce Clause argument.

First of all the rebate provision is designed to ensure lower prices for patients in Maine, it is directed towards obtaining lower prices in Maine for drugs and the Supreme Court in the *Brown-Forman* case stated, a state can seek lower prices for its citizens so long as it does not insist that producers or

consumers in other states surrender their relative competitive advantage.

Maine is not asking a consumer or producer in any other state to surrender any advantage that it might have.

Manufacturers are free to negotiate whatever price they want with respect to drugs sold in other states, and the consumers in other states are free and unrestrained by Maine statute to negotiate the best deal that they can. The statute does not co-op advantages enjoyed by those in other states. And for that reason, and for the reason that we have included in our papers, the Seventh Circuit decision in *K-S Pharmacies*, there is no objectionable Interstate Commerce of Maine's rebate program.

THE COURT: I understand your argument that there is no competitive disadvantage but the plaintiff has made two other arguments.

One, the extraterritoriality and the other is benchmark. Hasn't Maine gone outside its borders to control the transaction between the manufacturer and distributor in Kentucky or in Connecticut?

MR. HAGLER: By adopting a federal benchmark?

THE COURT: By providing that when the drugs ultimately end up in Maine that out-of-state manufacturer has to cough up some money to the State of Maine?

MR. HAGLER: The State of Maine is not regulating any transaction.

THE COURT: This is the market participant?

MR. HAGLER: No, your Honor, I make it in both areas. The State of Maine is not regulating any transaction outside of the State of Maine and it is not benchmarking its price to the price that pertains in any other state.

THE COURT: Let's put benchmarking aside for the moment. If XYZ Pharmaceutical company of New Jersey

sells to ABC distributor in Connecticut for $100 and then that drug ends up in Maine to be bought by a Maine consumer, doesn't Maine contemplate that the manufacturer has got to turn over some of that $100 to the State of Maine?

MR. HAGLER: Absolutely not.

THE COURT: And it has not gone outside its borders to regulate? The transaction for which that manufacturer thought it was getting $100 for the sale of that drug turns out to be $50.

MR. HAGLER: No. It has gotten $100 but it has elected to pay a rebate.

THE COURT: You used the word elected, is that important?

MR. HAGLER: If it enters into a rebate agreement, it's required to make the payment. The transaction between the manufacturer and it's out of state distributor remains the same. The plaintiff argues that this is the same as reducing or directly interfering or rewriting the contract which is out-of-state between the wholesaler and the manufacturer. But in *K-S Pharmacy* the Seventh Circuit said that an upstream effect on a wholesale manufacturer impose a have the do under transaction which happens to occur outside of the state which has the statute, does not implicate the Commerce Clause in a way which even requires balancing under the Pipe test.

THE COURT: How is this any different than it may duty on all drugs coming in the State of Maine and proceeds go to the Rx, which I take it Maine cannot the state commerce?

MR. HAGLER: You ask me an interesting question that I don't have a ready answer for it. I don't know that the state could be enjoined from a tax on a motion for Preliminary Injunction.

THE COURT: That may well be under the tax injunction provision. But I'm asking in a constitutional sense.

MR. HAGLER: And I think that if there is no difference, what the Court needs to consider is what the purpose is of what has been labeled as the Dormant Commerce Clause. And the purpose of the Dormant Commerce Clause, as the Supreme Court has articulated that in a variety of cases, is that the state cannot co-op for its self advantages which are in other markets, and Maine has not done that.

THE COURT: Your argument, if I understand from your papers and what you are saying now, the purpose of the Commerce Clause restrictions are to avoid discrimination and there is nothing discriminatory about Maine's statute; is that correct?

MR. HAGGLER: That's correct. And also that the State of Maine is not trying to obtain advantages like in the *Healy* and *Brown-Forman* that inure in other markets for itself. That is slightly different than discriminating from out-of-state and in state transactions. That is not allowing there to be a market occurring in different states throughout the nation that work according to their own competitive advantages. And Maine is not doing that, there is nothing about the rebate which injects Maine into the state of Vermont, or Massachusetts, or New Hampshire.

THE COURT: The other arguments Mr. Rugg has made is the benchmark argument, would you like to address that?

MR. HAGLER: Yes, thank you your Honor. Maine statute does not tie the rebate it seeks to obtain or the rebate it must obtain to the federal rebate. In other words, Commissioner Concannon is authorized by the statute to negotiate with drug companies for a rebate. And the statute does indeed suggest to the commissioner that he should use his best efforts to negotiate a rebate with drug companies that is better than or as good as the rebate which the state gets for those same drugs in the Medicaid program. But we are not tieing the rebate that the Commissioner must receive to that amount.

Now, of course the Commissioner began the negotiations, actually he began negotiations one step in the court of the drug companies because he did not ask for a rebate better than a Medicaid rebate. He submitted a proposal requesting a rebate in the Maine Rx or equal to the federal Medicaid rebate. The statute allows him of course to seek better, but the statute also permits the results that the rebate negotiated between the state and a particular drug company not be the federal benchmark. So, it is not correct to state that Maine is tieing its price or it's rebate in the Maine Rx program to the federal rebate. It is certainly looking to it, but even if it were so that the state were tieing it's rebate to the federal benchmark, again that is not a price that exists, the test of a price, that is not an attempt to obtain for Maine a price that another state was able to negotiate. There is no case of which I'm aware of that says using or even tieing a rebate to a federal benchmark is unconstitutional under the *Healy* and *Brown-Forman* cases. Those cases involve tieing prices in the regulating state with those of a particular state, or with those of the lowest of three bordering states but not an average. And I would submit that the use of an average does not enter in a Commerce Clause.

I will now turn to the market participation argument, your Honor.

Again, plaintiff must show a strong likelihood of succeeding on the merits. There is a complete defense, if you will, that the state has pled and argued in its papers and that is called the market participation exception. And the doctrine that has been developed by the Supreme Court has been that where a state acts as a market participant, actions which might in some fashion interfere with Interstate Commerce or interact or burden the state Interstate Commerce do not, because the state is not regulated, in fact act as market participant. There are two cases which we have pointed your Honor to, *Hughes versus Alexandria Scrap* case and *White versus Massachusetts*, and they are analogous to what Maine

is doing in that, and because in all instances the state is a purchaser.

And in Maine, here Maine purchases a very large quantity of drugs, 100 million dollars of drugs in the Medicaid program. I believe last week I was told the amount of the drugs purchased in the Medicaid program last week were 4 million dollars, just for the week. And last year at the same time the average was about 3 million dollars I believe. So it is an increasing amount and Maine is an important participant in that market, and it is using its market power to attempt to leverage it to obtain lower prices for other constituents in the state.

THE COURT: That's what Mr. Rugg says has gone too far. There is no question Maine is using its market power, given the large scale purchases you have described. And the cases you refer to, for example the White case in Boston who limited its construction projects to firms that employed 90 percent Boston residents, I think. And in the Hughes case, Maryland made it easier for in state owners to sell junk cars—

Mr. Rugg is saying what Maine is doing here, it is trying to use its leverage to effect something else, namely these uninsured-- how do you respond to that?

MR. HAGLER: The *White* case is most instructive because a narrow view—well, Mr. Ruggs says they're not in that market. In White the state of Massachusetts or the city of Boston was in the purchase of construction, they were hiring construction companies. One could argue that they are not in the market of hiring employees, they are in the market of hiring companies to go and build a public works program. But there is a separate market which the City of Boston does not have privity, if you will, in a contract sense, it is not in the market for construction for the employees that those construction companies hire, yet it was able to dictate beyond the purchase of construction contracts where the employees resided and the make up of the work force.

And we would argue the market that Maine is engaged in is the purchase of drugs and it's attempting to use its force to purchase drugs to lower prices for other people whom are in a sense a very closely related to the State of Maine, citizens who don't have drug insurance. And in a sense those other people are potential recipients of Medicaid dollars because if they go to the doctors and they can't afford to purchase the drugs, if they split prescriptions because of the high price, they can't afford them, it's possible they get sicker and are not able to work and find themselves in a situation of becoming eligible to receive Medicaid.

THE COURT: How do you distinguish the Supreme Court decision in the Alaska case?

MR. HAGLER: I argue it is hard to make an analogy to that case because Alaska was selling raw materials and in effect it was saying, further on you can't do something with that raw material, process that raw material in some other state, so vis-a-vis those other processors, and processors in other states, you are discriminating against these states and interstate commerce, that would be another way to distinguish that case.

And finally, your Honor, there's the Pipe balancing test and it is the State's position, and I want to make sure it is clear, that the Court need not get to the Pipe balancing test in order to rule for the state.

As I have argued earlier, we believe that there is no affect on Interstate Commerce, no affect on the rebate program that implicates interstate Commerce laws. But even though there is, again the state's interest vastly exceeds any effect on Interstate Commerce. Again, people are getting sick or getting sicker because they cannot afford their prescription drugs and we believe that when the balance is presented to the Court with facts in this case, that the interest of the state in passing this statute, the interest of its consumers of prescription drugs will so outweigh whatever minimal effect

plaintiff might prove on interstate commerce, and indeed plaintiff's claim that it has an affect on Interstate Commerce, that this statute has an affect on wholesale transaction is unquantified. There is nothing in the record which establishes a link to the size of the harm on Interstate Commerce that plaintiffs don't even flush out in their papers of facts. For that reason I believe that we will ultimately prevail on the Pipe test if the Court gets to that test.

For all of the foregoing reasons, unless your Honor has questions, the injunction ought to be denied.

THE COURT: I have a few questions. First of all does the LCD program have any bearing or does it simply happen to be in the statute, 'low cost for the elderly.

MR. HAGLER: It's another statute like the Maine Rx statute and also like Medicaid which uses the rebate mechanism.

The difference between the drugs for the elderly statute and the Maine Rx statute is that in the drugs for the elderly statute the State of Maine pays a portion, I don't believe all, a portion of the cost of the drugs. And I also believe without federal participation but I might be wrong on that.

THE COURT: It subsidizes?

MR. HAGLER: It's a subsidy, correct.

THE COURT: My second question is as to the anti-profiteering prohibition. You have argued that the rebate program is not extraterritoriality legislation because ultimately the consumer in Maine is ineffective—but if in fact the plaintiffs are correct that the vast majority of the manufacturer's sales distributors are outside the State of Maine, can Maine put a prohibition on the prices that they charge in New Jersey, Connecticut or elsewhere?

MR. HAGLER: I don't know that the statute prohibits—but it's possible. I take what your Honor is getting at is that

we could bring an action against the drug companies for prices which pertain in New Jersey or in some other state. I don't believe that the statute would be so utilized.

THE COURT: Then how would it be utilized? What do you understand to be the significance of that provision?

MR. HAGLER: The problem is, there has not been an investigation as contemplated by the statute. There hasn't been affirmative steps of which I'm aware to institute an action under that statute to flush out the facts. It is difficult enough to deal with the facts on the Preliminary Injunction with respect to the legality of the rebate provision than to contemplate what might occur, and what the facts might be in an action under that provision.

THE COURT: Mr. Rugg tells me the commissioner has alluded to that provision in his negotiating strategy.

MR. HAGLER: I would urge your Honor to read the letter that the commissioner has sent.

THE COURT: I will.

MR. HAGLER: I know how the manufacturer characterized it and how the state would respectfully characterize it as a little bit informative and a little bit bargaining but I don't think it's a threat.

THE COURT: Thank you very much. Mr. Rugg, rebuttal?

MR. RUGG: Yes, your Honor, I'd be happy to start with the LCD program. May I have just a moment?

THE COURT: Yes.

MR. RUGG: Your Honor, the statute makes it mandatory now if you look at the provision of the statute that defines rebate agreement, that is 2681 paragraph 3, it triggers the requirement to participate in a rebate program. I'm not sure that I am precisely answering the Court's question but our argument is that this, it intercepts with the rebate provision of

the statute which is subject to all the constitutional challenges we have been discussing.

THE COURT: I have two questions.

MR. RUGG: Yes sir.

THE COURT: Are you challenging anything concerning the LCD program or can I ignore it or is it not before me?

MR. RUGG: I believe it is not before you.

I have heard an awful lot of lawyers say they only have two questions, at least now I've heard judges can limit themselves to that limitation.

THE COURT: Sometimes.

MR. RUGG: Your Honor, with respect to Mr. Hagler's argument, it started and ended with the issue of how serious the harm is here to the citizens of this state. Drug prices are a serious issue. They are a serious issue that is addressed in all public forms presently, from presidential debates to state houses. We acknowledge the importance of this. It is a national issue. But the remedy that this state has selected, that is most poignantly described by Senator Pingree, is unconstitutional because this state says we can save the misery that our residents are suffering by violating the Constitution of the United States.

I respectfully submit to the Court it is not a proper issue in this case to weigh the hardship of uninsured residents struggling to acquire necessary medications, to weigh that against the constitutional imperatives here.

I would like to address the prior authorization.

We believe, and if the Court would like us to brief this, we would be happy to do so.

We believe that the draft HCFA regulations are informative but are not authoritative, not having been for purposes of a Chevron analysis.

We believe the Court does not have authoritative regulations before it.

What the Court does have is commentary that the state relies on.

You will recall Mr. Hagler saying, characterizing the commentary as what ifs, and responses. Well there are two conclusions.

One is: Clinical decisions should drive prior authorization.

And the second is if we depart from clinical to consider economic, economic is proper within the contents of the Medicaid statute. This state has an interest under the Medicaid statute of maximizing value for medicaid recipients in this state and that is the beginning and the end of that commentary.

We do not contend that the state is going to make prior authorization decisions under the Maine program that will deprive patients of the one drug that they have to have. Mr. Hagler talked about the aids patient or the cancer patient. How about the dozens of antibiotics that are in the market place that prior to enactment of the statute were not subject to prior authorization? But suddenly, with this statute, they are subject to prior authorization for only one reason: To compel participation in the program. And that, your Honor, has nothing to do with the federal program. That is the nub of our argument.

We concede the statute does not say no state shall use prior authorization as a gun to force people to participate in unrelated local programs but it should be self evident.

Your Honor, unless the Court has other questions of me, I thank you very much.

THE COURT: Thank you. Counsel, your arguments have been enormously helpful to me, they were both well prepared and you have presented the case well. Two or three questions

did come up during argument and if either of you want to elaborate briefly on them in the record, or add to your briefs filed originally, I would like to ask them to be filed by Monday. I know that does not give you much time but I know that you also want a decision from me quickly. If there are citations or that you feel you were not able to answer questions I had, then by a brief response I will accept that and I will use it.

Again, I thank you very much, the case has been thoroughly presented and as soon as I have whatever additional submissions, I will proceed to enter a decision as soon as possible. Thank you very much. The Court is in recess.

(Whereupon the Court recessed at 10:33 AM)

CERTIFICATE

I hereby certify the foregoing is a true and accurate transcript of my stenographic notes taken at the time and place herein set forth.

Dated at Portland, Maine this 19th day of October 2000.

/s/
Official Court Reporter

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October 23, 2000

Honorable D. Brock Hornby
Chief U.S. District Judge
United States District Court
156 Federal Street
Portland, ME 04101

Re: *Pharmaceutical Research and Manufacturers of America v. Kevin Concannon, et al.*
Docket No. 00-CV-157-B-H

Dear Judge Hornby:

This letter is submitted in response to your invitation to counsel for the parties, at the close of oral argument on Thursday, October 19, 2000, to address in writing certain issues that arose during that hearing. We appreciate this opportunity and hope that the following clarifications will be of assistance to the Court.

Proposed Regulations of HCFA and the Maine Department of Human Services

The Court raised questions during the hearing concerning the legal significance of (a) the federal Health Care Financing Administration's ("HCFA") proposed regulations implementing the Medicaid prescription drug benefit 60 Fed. Reg. 48,442 (Sept. 19, 1995), and (b) the Maine Department of Human Services' proposed regulations implementing prior authorization under the Maine Rx program, a copy of which was filed with the Court on October 19, 2000.

The Court inquired about the deference due, if any, to HCFA's proposed regulations under the rubric of *Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984). Legal precedents confirm that proposed (rather than final) regulations and interpretive commentary are not owed *Chevron* deference. *See e.g., Tedori v. United States*, 211 F.3d 488, 492 & n.13 (9th Cir. 2000) (stating that "proposed regulations carry no more weight than a position advanced on brief") and cases cited therein; *Teweleit v. Hartford Life & Accident Ins. Co.*, 43 F.3d 1005 (5th Cir. 1995) (stating that a regulation never adopted "thus has no precedential authority"). Last term, the Supreme Court indicated that *Chevron* deference is reserved for administrative interpretations formally arrived at "after, for example, a formal adjudication or notice-and-comment rulemaking." *Christensen v. Harris County*, 120 S. Ct. 1655, 1662-63 (2000) (rejecting *Chevron* deference to an interpretation in an opinion letter). Accordingly, PhRMA respectfully suggests that proposed regulations warrant the Court's consideration only to the extent that they are persuasive, *Christensen*, 120 S. Ct. at 1663; no deference is required or appropriate.

It was for their persuasive force that PhRMA's Motion invited the Court's attention to HCFA's proposed regulations, and particularly to HCFA's goal of ensuring that any use of prior authorization has "medical necessity as its *primary* concern." PhRMA Motion at 17-18, discussing 60 Fed. Reg. at 48,454-55 (emphasis added). Maine's new use of prior authorization has the Maine Rx program's funding, not medical necessity for Medicaid patients, as its primary concern. PhRMA maintains that the inconsistency between HCFA's stated goal and that of the Maine Rx program is evidence of the latter's conflict with congressional objectives.

Even as persuasive authority, the HCFA proposed regulations cannot be stretched beyond their logical boundaries. At oral argument, the State referred the Court to

HCFA commentary suggesting that a state could take not only clinical but also economic considerations into account in imposing prior authorization. *See* 60 Fed. Reg. at 48473. HCFA's comments, however, are addressed to economic considerations germane to the Medicaid program, and only the Medicaid program. As HCFA recognized, it is certainly appropriate for state Medicaid authorities to consider economic criteria in prior authorization *for the benefit of the Medicaid program*. But HCFA never suggested that it would be appropriate to consider economic criteria *unrelated to Medicaid*—such as funding non-Medicaid programs like Maine Rx—in imposing prior authorization.

The Court also asked whether draft Maine Rx regulations on prior authorization could cure the statute's infirmities under the Supremacy Clause alleged by PhRMA. PhRMA contends that, whether proposed or final, the Department's regulations cannot save the Maine Rx prior authorization requirement from preemption. The State has not contested that prior authorization imposes a procedural burden on Medicaid doctors and patients, and consumes Medicaid resources (*e.g.* the time and resources of the Medicaid Drug Utilization Review Committee); in fact, the State outlined that burdensome process in some detail at oral argument, *see* Tr. 26-27. PhRMA maintains that the very imposition of that burden, for reasons unrelated to any Medicaid purpose, conflicts with the federal Medicaid program. Regardless of how State regulations implement Maine Rx prior authorization, that burden serves no Medicaid purpose and works to the detriment of the Medicaid program and its beneficiaries. PhRMA respectfully suggests that the State's regulations are of marginal relevance at best, not because they are merely proposed and not final, but because they do not cure the Maine Rx statute's preemption in any event.

Mandatory Participation in the Maine Rx Rebate Program

At oral argument, the State responded to a question from the Court regarding the alleged extraterritoriality of the Maine

Rx rebate program by suggesting that manufacturers would "elect" to pay the rebates. Any suggestion that the Maine Rx program is somehow voluntary simply misperceives the statute. The statute specifically mandates tat manufacturers "*shall* enter into [] rebate agreement[s]" (emphasis supplied) and sets out severe penalties (prior authorization, negative publicity, and profiteering prosecutions) for any manufacturer who does not comply with the statute. Further, the rebate program is not a "negotiation," as the State suggests; the statute does not give manufacturers the option of failing to reach an agreement. Manufacturers thus cannot "elect" not to pay Maine Rx rebates.

Situs of Prescription Drug Sales

Several colloquies with the Court centered on the significance of the situs of manufacturers' prescription drug sales. In connection with its extraterritoriality challenge, PhRMA maintains that sales taking place outside Maine cannot, consistent with the Commerce Clause, be subject to the Maine Rx rebate requirement.

The situs of sales, moreover, relates to the ripeness of PhRMA's challenge to the anti-retaliation provision of the statute: manufacturers are presently precluded from shifting those in-state sales that they do make (if any) to out-of-state distribution channels. The law's interference with the mobility of interstate commerce is especially immediate if the anti-retaliation provision prevents manufacturers from shifting the situs of their in-state sales (if any) to take advantage of a ruling from this Court that the Maine Rx rebate cannot be applied to out-of-state sales.

LCD Program

To clarify our response to a question from the Court regarding Maine's Elderly Low Cost Drug Program, PhRMA confirms that the LCD program is not at issue in its motion for a preliminary injunction, and thus is not before the Court at this time.

We thank the Court for the opportunity to appear before it last week, and for this opportunity to supplement and clarify the record.

Respectfully submitted,

/s/
Bruce C. Gerrity

BCG/rgy
cc: Andrew S. Hagler, Esq.

STATE OF MAINE
DEPARTMENT OF THE ATTORNEY GENERAL
6 STATE HOUSE STATION
AUGUSTA, MAINE 04333-0006

October 23, 2000

The Honorable D. Brock Hornby
Chief U.S. District Judge
156 Federal Street
Portland ME 04101

Re: *Pharmaceutical Research v. Concannon, et al.*
Case No.: 00-157-B

Dear Judge Hornby:

We appreciate the opportunity to submit additional briefing on issues raised by the Court but not fully addressed during the hearing of October 19, 2000.

At the hearing the Court asked what might be the effective date of the proposed rules implementing the Maine Rx program. The notice of rulemaking was filed with the Secretary of State on October 10, 2000. Pursuant to the Maine APA, a public announcement was posted in newspapers on October 18. A public hearing is scheduled for Wednesday November 8, 2000, and written comments from the public are due no later than November 20, 2000. The rules can become effective as soon as any responses to the comments and/or minor revisions to the proposed rules are completed, and the review of the Attorney General is obtained. While the ultimate effective date may be as long at 155 days from the public comment deadline, the Department intends to complete the rulemaking process no later than January 1, 2001 so that the rules are in effect when the Maine Rx Program begins.

The remainder of this letter addresses: 1) the application of *Chevron* principles to rules of a federal agency that have been

proposed but not adopted, and 2) whether the Maine Rx Program imposes a "duty."

1. *It Is Unnecessary To Accord Special Deference Under Chevron To The Proposed Rules Promulgated By The Federal Health Care Financing Administration.*

Both parties have called the Court's attention to proposed rules of the Health Care Financing Administration ("HCFA") entitled *Medicaid Program Payment for Covered Outpatient Drugs Under Drug Rebate Agreements with Manufacturers*, 60 Fed. Reg. 48,442 (Sept 19, 1995). In its initial brief, Plaintiff contended that HCFA proposed rules support its contention that the use of prior authorization in the fashion contemplated by the Maine Rx program would defeat Congress's intent to "assur[e] access by Medicaid beneficiaries to prescription drugs where medically necessary." *Plaintiff's Memorandum of Law* at 17.

During the hearing on October 19, defendants cited a different portion of the same proposed rules to demonstrate that HCFA's interpretation actually supports the State's position. First, according to HCFA, "[s]tates should be able to consider both clinical and economic criteria in their prior authorization programs as long as medically necessary drugs are not denied." 60 Fed. Reg. 48,442 at 48,447. Second, HCFA apparently agrees that a State can use its prior authorization power to attempt to negotiate for itself further financial benefits from drug manufacturers beyond those provided by the "national" Medicaid rebates negotiated by HCFA. *Id.*

Maine submits that HCFA agrees with the underlying premise of our preemption argument — that Congress did not intend to impose any requirement on the use of the prior authorization power it gave to the states other than the two, ministerial requirements specifically set forth in the statute. 42 U.S.C. 1396r-8(d)(5). To te extent that the requirement that Medicaid recipients receive "medically necessary" drugs

is viewed as a further restriction on the use of prior authorizations, the Maine Rx statute only authorizes imposition of prior authorization requirement "as permitted by law", and the Department's proposed rules ensure that all medically necessary drugs will be dispensed.

The State does not believe that Congress's intent with respect to prior authorizations is ambiguous. The proposed rules reflect this clarity but it is not necessary to resort to any statement by HCFA to discern Congressional intent. The State cited HCFA's proposed rules primarily to rebut Plaintiffs assertion that the proposed rules require a finding that Congress intended to greatly limit the use of prior authorizations. In short, the question of whether proposed rules, as opposed to *final* rules, are to be afforded deference pursuant to *Chevron U.S.A. Inc. v. Natural Resources Defense Council*, 467 U.S. 837 (1984), need not be reached. However, if congressional intent were not manifest by the statute itself, HCFA's proposed rules are instructive for the proposition that Congress did not intend to limit use of prior authorizations other than in the limited fashion specifically set forth in the Medicaid statute.

2. *The Rebate Agreement Does Not Constitute A "Duty."*

At the October 19 hearing, the Court asked whether the Maine Rx Program rebates could be compared to an impermissible duty on the importation of drugs.

The Maine Rx Program rebate is not a duty, for several reasons. The rebates do not discriminate against out-of-state goods. The Commissioner is directed to negotiate rebate agreements with all drug manufacturers, irrespective of where the manufacture is located and where its drugs come to Maine from. The Act applies equally to out-of-state drug manufacturers and to any manufacturers which are located in Maine now or in the future. The purpose of the Maine Rx Program is not to discriminate among goods based upon their source. Rather, the rebates are intended to assist the State in

lowering the prices of drugs made by participating manufacturers.

Also, duties, like other taxes, generally apply at a uniform rate across all goods and all taxpayers. Here, however, the Act contemplates negotiation of the rebate by each participating manufacturer. Moreover, not all drugs of a participating manufacturer that enter into the State are subject to a rebate. Instead, only drugs which are ultimately purchased by an uninsured citizen at a pharmacy trigger a rebate payment.

Finally, governments generally enforce the obligation to pay a duty with either criminal or civil sanctions, or by prohibiting the entry of the good. Here, however, the only consequence of failing to negotiate a rebate agreement is the possibility that certain drugs of a manufacturer will be subject to prior authorization requirements before they are reimbursed through the Maine Medicaid program.

For these reasons, rebate payments made pursuant to agreements negotiated between the Commissioner and pharmaceutical manufacturing companies cannot be considered a "duty." As noted at the hearing, however, if the rebate agreement contemplated by the statute is somehow determined to be a form of taxation, the federal district courts lack jurisdiction to grant the requested injunction under the Tax Injunction Act, 28 U.S.C. § 1341.[1]

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[1] Even if the rebate agreements were considered a "tax," the Commerce Clause does not prohibit state taxes that have some extraterritorial reach. In *Complete Auto Transit, Inc. v. Brady*, 430 U.S. 274 (1977), the Supreme Court determined that a state tax will be sustained so long as it (1) is applied to an activity with a substantial nexus with the taxing state; (2) is fairly apportioned; (3) does not discriminate against interstate commerce; and (4) is fairly related to the benefits received by the taxpaying entity from access to the state. *See also Quill Corp. v. Heitkamp*, 504 U.S. 298 (1992). The *Complete Auto Transit* analysis would necessarily entail considerable factual inquiry in this case. For instance, even though Plaintiff has alleged that very few of its wholesale

Thank you for considering these additional comments.

Very truly yours,

/s/
Andrew S. Hagler
Assistant Attorney General

/s/
John Brautigam
Assitant Attorney General

transactions occur in Maine, it is likely that individual drug manufacturers engage in sufficient sales and promotion activity within the State to satisfy the "substantial nexus" prong of the *Complete Auto Transit* test.

UNITED STATES DISTRICT COURT
DISTRICT OF MAINE

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA,

PLAINTIFF

v. Civil No. 00-157-B-H

COMMISSIONER, MAINE DEPARTMENT OF HUMAN SERVICES, ET AL.,

DEFENDANTS

ORDER ON MOTION TO INTERVENE

On October 26, 2000, I granted a preliminary injunction in favor of the plaintiff against specified parts of Maine's prescription drug pricing legislation. On November 9, 2000, the state defendants appealed. On November 13, 2000, certain would-be intervenors filed a motion to intervene under Fed. R. Civ. P. 24, along with a motion to alter or amend judgment and motion to dismiss Count V of the plaintiff's Complaint. They also requested that I grant them an extension of time, if they are allowed to intervene, to file their own notice of appeal from the preliminary injunction of October 26, 2000. These would-be intervenors have previously participated in the lawsuit by filing an *amicus* brief.

The law on this subject—private plaintiffs attempting to intervene in support of state legislation at the same time the Maine Attorney General is defending the legislation—is well established in this Circuit. *See Daggett v. Comm'n on Gov't Ethics & Election Practices*, 172 F.3d 104, 109-111 (lst Cir. 1999). For intervention as of right, I examine four factors: timeliness; interest in the property or transaction that is the

subject of the lawsuit; effect on ability to protect that interest; and adequacy of representation.

(1) The motion to intervene is timely as to any further proceedings in this trial court because at this point no scheduling order has been entered, no discovery has taken place and the lawsuit is only beginning. It is untimely, however, as to the preliminary injunction issues. Those issues were fully briefed and argued orally following conferences with the Court in preparation for those events. There was abundant opportunity for the intervenors to have moved earlier to intervene. The preliminary injunction has now issued and been appealed and a briefing schedule has been set for the appeal. There is no good excuse for the intervenors not to have moved to intervene earlier if preliminary injunction was their concern.

(2) The would-be intervenors have a distinct and real interest in the lawsuit. Specifically, they are two individuals who cannot otherwise afford needed prescription medication, a membership-based organization that advocates on behalf of Maine's seniors particularly with regard to affordable healthcare, and a family practice physician whose prescription practices are affected by the ability of his patients to pay for medication.

(3) Disposition of this lawsuit will undoubtedly affect dramatically the proposed intervenors' ability to protect their interests because the constitutionality of Maine's attempt to lower the prices for prescription drugs will be determined by the outcome.

(4) As in *Daggett*, the primary issue is adequacy of representation. 172 F.3d at 111 (noting that the "heart of the case" is whether the Attorney General adequately represented their interests). Here, as in *Daggett*, the Attorney General's Office is aggressively defending the statute. Unlike *Daggett*, this statute did not result from a citizen initiative, but is a statute actively supported by the Governor and the

Legislature. The would-be intervenors argue that because their health is at stake the normal presumption in favor of adequate representation by the Attorney General should be reduced. But I do not rely on presumption. The Attorney General is vigorously defending the case, far more than just "adequately." In addition, they point to two arguments they want to make that the Attorney General has not made. The first argument—that the plaintiff is not irreparably harmed—goes only to the preliminary injunction where, I have concluded, the motion to intervene is untimely. The second argument goes to the merits. The intervenors want to argue that the plaintiff has no standing to make its supremacy challenge based upon federal Medicaid law, an argument that the State did not make at the time of preliminary injunction arguments. As in *Daggett*, however, such tactical disagreements are not enough to require intervention as of right automatically. 172 F.3d 104, 112 (1st Cir. 1999). The refusal to present an obvious argument must be "extreme." *Id.* These would-be intervenors can present their argument fully and ably through *"amicus* plus" status, which I now grant them. Unlike factual development, it does not require intervenor status. Moreover, it may well be that the State will see fit to adopt the argument on the merits after the preliminary injunction stage. Lawyers must make tactical and strategic choices as to what arguments to press given the limits of time for oral arguments and page limits for briefs. The fact that a lawyer chooses not to make a particular argument at a given stage does not demonstrate inadequacy of representation. Instead, the record makes abundantly clear that the Attorney General is vigorously defending this legislation with the full support of state government.

Finally, permissive intervention serves no useful purpose here where *amicus* plus status is granted and the Attorney General is representing all the interests of the State in defending the legislation. I make the following Order as I did in *Daggett v. Webster*, 190 F.R.D. 12 (D. Me. 1998).

1. Notice and service of all documents and events shall be given to the would-be intervenors' counsel just as if they were parties in the case.

2. If there are witnesses at trial or deposition where the Attorney General's Office is willing to let the would-be intervenors' lawyer conduct the examination or cross-examination in place of an Assistant Attorney General, that is permitted. What is not permitted is examination or cross-examination by both.

3. I expect that, as appropriate, the Attorney General's Office will take full advantage of any offer of resources, evidence or assistance from the would-be intervenors where to do so will help the Attorney General defend the constitutionality of the statute.

4. Finally, the motion to intervene can be renewed if and when the would-be intervenors have evidence that the case is not being fully and properly presented by the Attorney General.

For these reasons, the motion to intervene is *DENIED* and the motion for extension of time to file a notice of appeal is *DENIED* because I have denied the motion to intervene. No action is necessary on the motion to alter or amend judgment and to dismiss Count V of the plaintiffs Complaint.

SO ORDERED.
DATED THIS *14th* OF DECEMBER, 2000.

/s/

D. Brock Hornby
United States District Judge

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SOCIAL SECURITY ACT § 1927
42 U.S.C. §§ 1396, 1396a(a)(10)(A)-(C), (a)(19), (a)(30)(A)-(B) & (a)(54), 1396c, 1396d(a) & 1396r-8(g)

42 USCA § 1396: Appropriations

For the purpose of enabling each State, as far as practicable under the conditions in such State, to furnish (1) medical assistance on behalf of families with dependent children and of aged, blind, or disabled individuals, whose income and resources are insufficient to meet the costs of necessary medical services, and (2) rehabilitation and other services to help such families and individuals attain or retain capability for independence or self- care, there is hereby authorized to be appropriated for each fiscal year a sum sufficient to carry out the purposes of this subchapter. The sums made available under this section shall be used for making payments to States which have submitted, and had approved by the Secretary, State plans for medical assistance.

42 USCA § 1396a: State plans for medical assistance

(a) Contents

A State plan for medical assistance must—

* * * *

(10) provide—

(A) for making medical assistance available, including at least the care and services listed in paragraphs (1) through (5), (17) and (21) of section 1396d(a) of this title, to—

(i) all individuals—

(I) who are receiving aid or assistance under any plan of the State approved under subchapter I, X, XIV, or XVI of this chapter, or part A or part E of subchapter IV of this chapter (including

individuals eligible under this subchapter by reason of section 602(a)(37) 606(h), or 673(b) of this title, or considered by the State to be receiving such aid as authorized under section 682(e)(6) of this title),

(II) with respect to whom supplemental security income benefits are being paid under subchapter XVI of this chapter (or were being paid as of August 22, 1996) and would continue to be paid but for the enactment of that section or who are qualified severely impaired individuals (as defined in section 1396d(q) of this title),

(III) who are qualified pregnant women or children as defined in section 1396d(n) of this title,

(IV) who are described in subparagraph (A) or (B) of subsection (l)(1) of this section and whose family income does not exceed the minimum income level the State is required to establish under subsection (l)(2)(A) of this section for such a family;

(V) who are qualified family members as defined in section 1396d(m)(1) of this title;

(VI) who are described in subparagraph (C) of subsection (l)(1) of this section and whose family income does not exceed the income level the State is required to establish under subsection (l)(2)(B) of this section for such a family, or

(VII) who are described in subparagraph (D) of subsection (l)(1) of this section and whose family income does not exceed the income level the State is required to establish under

subsection (l)(2)(C) of this section for such a family;

(ii) at the option of the State, to any group or groups of individuals described in section 1396d(a) of this title (or, in the case of individuals described in section 1396d(a)(i) of this title, to any reasonable categories of such individuals) who are not individuals described in clause (i) of this subparagraph but—

(I) who meet the income and resources requirements of the appropriate State plan described in clause (i) or the supplemental security income program (as the case may be),

(II) who would meet the income and resources requirements of the appropriate State plan described in clause (i) if their work-related child care costs were paid from their earnings rather than by a State agency as a service expenditure,

(III) who would be eligible to receive aid under the appropriate State plan described in clause (i) if coverage under such plan was as broad as allowed under Federal law,

(IV) with respect to whom there is being paid, or who are eligible, or would be eligible if they were not in a medical institution, to have paid with respect to them, aid or assistance under the appropriate State plan described in clause (i), supplemental security income benefits under subchapter XVI of this chapter, or a State supplementary payment;

(V) who are in a medical institution for a period of not less than 30 consecutive days (with eligibility by reason of this subclause beginning on the first day of such period), who meet the

resource requirements of the appropriate State plan described in clause (i) or the supplemental security income program, and whose income does not exceed a separate income standard established by the State which is consistent with the limit established under section 1396b(f)(4)(C) of this title,

(VI) who would be eligible under the State plan under this subchapter if they were in a medical institution, with respect to whom there has been a determination that but for the provision of home or community-based services described in subsection (c), (d), or (e) of section 1396n of this title they would require the level of care provided in a hospital, nursing facility or intermediate care facility for the mentally retarded the cost of which could be reimbursed under the State plan, and who will receive home or community-based services pursuant to a waiver granted by the Secretary under subsection (c), (d), or (e) of section 1396n of this title,

(VII) who would be eligible under the State plan under this subchapter if they were in a medical institution, who are terminally ill, and who will receive hospice care pursuant to a voluntary election described in section 1396d(o) of this title;

(VIII) who is a child described in section 1396d(a)(i) of this title—

(aa) for whom there is in effect an adoption assistance agreement (other than an agreement under part E of subchapter IV of this chapter) between the State and an adoptive parent or parents,

(bb) who the State agency responsible for adoption assistance has determined cannot be placed with adoptive parents without medical assistance because such child has special needs for medical or rehabilitative care, and

(cc) who was eligible for medical assistance under the State plan prior to the adoption assistance agreement being entered into, or who would have been eligible for medical assistance at such time if the eligibility standards and methodologies of the State's foster care program under part E of subchapter IV of this chapter were applied rather than the eligibility standards and methodologies of the State's aid to families with dependent children program under part A of subchapter IV of this chapter;

(IX) who are described in subsection (l)(1) of this section and are not described in clause (i)(IV), clause (i)(VI), or clause (i)(VII);

(X) who are described in subsection (m)(1) of this section;

(XI) who receive only an optional State supplementary payment based on need and paid on a regular basis, equal to the difference between the individual's countable income and the income standard used to determine eligibility for such supplementary payment (with countable income being the income remaining after deductions as established by the State pursuant to standards that may be more restrictive than the standards for supplementary security income benefits under subchapter XVI of this chapter), which are available to all individuals in the State (but which may be based on different income

standards by political subdivision according to cost of living differences), and which are paid by a State that does not have an agreement with the Commissioner of Social Security under section 1382e or 1383c of this title;

(XII) who are described in subsection (z)(1) of this section (relating to certain TB-infected individuals);

(XIII) who are in families whose income is less than 250 percent of the income official poverty line (as defined by the Office of Management and Budget, and revised annually in accordance with section 9902(2) of this title) applicable to a family of the size involved, and who but for earnings in excess of the limit established under section 1396d(q)(2)(B) of this title, would be considered to be receiving supplemental security income (subject, notwithstanding section 1396o of this title, to payment of premiums or other cost-sharing charges (set on a sliding scale based on income) that the State may determine);

(XIV) who are optional targeted low-income children described in section 1396d(u)(2)(B) of this title;

(XV) who, but for earnings in excess of the limit established under section 1396d(q)(2)(B) of this title, would be considered to be receiving supplemental security income, who is at least 16, but less than 65, years of age, and whose assets, resources, and earned or unearned income (or both) do not exceed such limitations (if any) as the State may establish;

(XVI) who are employed individuals with a medically improved disability described in section 1396d(v)(1) of this title and whose

assets, resources, and earned or unearned income (or both) do not exceed such limitations (if any) as the State may establish, but only if the State provides medical assistance to individuals described in subclause (XV);

(XVII) who are independent foster care adolescents (as defined in section 1396d(w)(1) of this title), or who are within any reasonable categories of such adolescents specified by the State; or

(XVIII) who are described in subsection (aa) (relating to certain breast or cervical cancer patients);

(B) that the medical assistance made available to any individual described in subparagraph (A)—

(i) shall not be less in amount, duration, or scope than the medical assistance made available to any other such individual, and

(ii) shall not be less in amount, duration, or scope than the medical assistance made available to individuals not described in subparagraph (A);

(C) that if medical assistance is included for any group of individuals described in section 1396d(a) of this title who are not described in subparagraph (A) or (E), then—

(i) the plan must include a description of (I) the criteria for determining eligibility of individuals in the group for such medical assistance, (II) the amount, duration, and scope of medical assistance made available to individuals in the group, and (III) the single standard to be employed in determining income and resource eligibility for all such groups, and the methodology to be employed in determining such eligibility, which shall be no

more restrictive than the methodology which would be employed under the supplemental security income program in the case of groups consisting of aged, blind, or disabled individuals in a State in which such program is in effect, and which shall be no more restrictive than the methodology which would be employed under the appropriate State plan (described in subparagraph (A)(i)) to which such group is most closely categorically related in the case of other groups;

(ii) the plan must make available medical assistance—

(I) to individuals under the age of 18 who (but for income and resources) would be eligible for medical assistance as an individual described in subparagraph (A)(i), and

(II) to pregnant women, during the course of their pregnancy, who (but for income and resources) would be eligible for medical assistance as an individual described in subparagraph (A);

(iii) such medical assistance must include (I) with respect to children under 18 and individuals entitled to institutional services, ambulatory services, and (II) with respect to pregnant women, prenatal care and delivery services; and

(iv) if such medical assistance includes services in institutions for mental diseases or in an intermediate care facility for the mentally retarded (or both) for any such group, it also must include for all groups covered at least the care and services listed in paragraphs (1) through (5) and (17) of section 1396d(a) of this title or the care and services listed in any 7 of the paragraphs numbered (1) through (24) of such section;

* * * *

(19) provide such safeguards as may be necessary to assure that eligibility for care and services under the plan will be determined, and such care and services will be provided, in a manner consistent with simplicity of administration and the best interests of the recipients;

* * * *

(30)(A) provide such methods and procedures relating to the utilization of, and the payment for, care and services available under the plan (including but not limited to utilization review plans as provided for in section 1396b(i)(4) of this title) as may be necessary to safeguard against unnecessary utilization of such care and services and to assure that payments are consistent with efficiency, economy, and quality of care and are sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area; and

(B) provide, under the program described in subparagraph (A), that—

(i) each admission to a hospital, intermediate care facility for the mentally retarded, or hospital for mental diseases is reviewed or screened in accordance with criteria established by medical and other professional personnel who are not themselves directly responsible for the care of the patient involved, and who do not have a significant financial interest in any such institution and are not, except in the case of a hospital, employed by the institution providing the care involved, and

(ii) the information developed from such review or screening, along with the data obtained from prior reviews of the necessity for admission and

continued stay of patients by such professional personnel, shall be used as the basis for establishing the size and composition of the sample of admissions to be subject to review and evaluation by such personnel, and any such sample may be of any size up to 100 percent of all admissions and must be of sufficient size to serve the purpose of (I) identifying the patterns of care being provided and the changes occurring over time in such patterns so that the need for modification may be ascertained, and (II) subjecting admissions to early or more extensive review where information indicates that such consideration is warranted to a hospital, intermediate care facility for the mentally retarded, or hospital for mental diseases;

* * * *

(54) in the case of a State plan that provides medical assistance for covered outpatient drugs (as defined in section 1396r-8(k) of this title), comply with the applicable requirements of section 1396r-8 of this title:

* * * *

42 USCA § 1396c: Operation of State plans

If the Secretary, after reasonable notice and opportunity for hearing to the State agency administering or supervising the administration of the State plan approved under this subchapter, finds—

(1) that the plan has been so changed that it no longer complies with the provisions of section 1396a of this title; or

(2) that in the administration of the plan there is a failure to comply substantially with any such provision;

the Secretary shall notify such State agency that further payments will not be made to the State (or, in his discretion,

that payments will be limited to categories under or parts of the State plan not affected by such failure), until the Secretary is satisfied that there will no longer be any such failure to comply. Until he is so satisfied he shall make no further payments to such State (or shall limit payments to categories under or parts of the State plan not affected by such failure).

42 USCA § 1396d: Definitions

For purposes of this subchapter—

(a) Medical assistance

The term "medical assistance" means payment of part or all of the cost of the following care and services (if provided in or after the third month before the month in which the recipient makes application for assistance or, in the case of medicare cost-sharing with respect to a qualified medicare beneficiary described in subsection (p)(1) of this section, if provided after the month in which the individual becomes such a beneficiary) for individuals, and, with respect to physicians' or dentists' services, at the option of the State, to individuals (other than individuals with respect to whom there is being paid, or who are eligible, or would be eligible if they were not in a medical institution, to have paid with respect to them a State supplementary payment and are eligible for medical assistance equal in amount, duration, and scope to the medical assistance made available to individuals described in section 1396a(a)(10)(A) of this title) not receiving aid or assistance under any plan of the State approved under subchapter I, X, XIV, or XVI, or part A of subchapter IV, and with respect to whom supplemental security income benefits are not being paid under subchapter XVI of this chapter, who are—

(i) under the age of 21, or, at the option of the State, under the age of 20, 19, or 18 as the State may choose,

(ii) relatives specified in section 606(b)(1) of this title with whom a child is living if such child is (or would, if

needy, be) a dependent child under part A of subchapter IV of this chapter,

(iii) 65 years of age or older,

(iv) blind, with respect to States eligible to participate in the State plan program established under subchapter XVI of this chapter,

(v) 18 years of age or older and permanently and totally disabled, with respect to States eligible to participate in the State plan program established under subchapter XVI of this chapter,

(vi) persons essential (as described in the second sentence of this subsection) to individuals receiving aid or assistance under State plans approved under subchapter I, X, XIV, or XVI of this chapter,

(vii) blind or disabled as defined in section 1382c of this title, with respect to States not eligible to participate in the State plan program established under subchapter XVI of this chapter,

(viii) pregnant women,

(ix) individuals provided extended benefits under section 1396r-6 of this title,

(x) individuals described in section 1396a(u)(1) of this title,

(xi) individuals described in section 1396a(z)(1) of this title,

(xii) employed individuals with a medically improved disability (as defined in subsection (v)), or

(xiii) individuals described in section 1396a(aa) of this title,

but whose income and resources are insufficient to meet all of such cost—

(1) inpatient hospital services (other than services in an institution for mental diseases);

(2) (A) outpatient hospital services, (B) consistent with State law permitting such services, rural health clinic services (as defined in subsection (l)(1) of this section) and any other ambulatory services which are offered by a rural health clinic (as defined in subsection (l)(1) of this section) and which are otherwise included in the plan, and (C) Federally-qualified health center services (as defined in subsection (l)(2) of this section) and any other ambulatory services offered by a Federally-qualified health center and which are otherwise included in the plan;

(3) other laboratory and X-ray services;

(4) (A) nursing facility services (other than services in an institution for mental diseases) for individuals 21 years of age or older; (B) early and periodic screening, diag-nostic, and treatment services (as defined in subsection (r) of this section) for individuals who are eligible under the plan and are under the age of 21; and (C) family planning services and supplies furnished (directly or under arrangements with others) to individuals of child-bearing age (including minors who can be considered to be sexually active) who are eligible under the State plan and who desire such services and supplies;

(5) (A) physicians' services furnished by a physician (as defined in section 1395x(r)(1) of this title), whether furnished in the office, the patient's home, a hospital, or a nursing facility, or elsewhere, and (B) medical and surgical services furnished by a dentist (described in section 1395x(r)(2) of this title) to the extent such services may be performed under State law either by a doctor of medicine or by a doctor of dental surgery or dental medicine and would be described in clause (A) if

furnished by a physician (as defined in section 1395x(r)(1) of this title);

(6) medical care, or any other type of remedial care recognized under State law, furnished by licensed practitioners within the scope of their practice as defined by State law;

(7) home health care services;

(8) private duty nursing services;

(9) clinic services furnished by or under the direction of a physician, without regard to whether the clinic itself is administered by a physician, including such services furnished outside the clinic by clinic personnel to an eligible individual who does not reside in a permanent dwelling or does not have a fixed home or mailing address;

(10) dental services;

(11) physical therapy and related services;

(12) prescribed drugs, dentures, and prosthetic devices; and eyeglasses prescribed by a physician skilled in diseases of the eye or by an optometrist, whichever the individual may select;

(13) other diagnostic, screening, preventive, and rehabilitative services, including any medical or remedial services (provided in a facility, a home, or other setting) recommended by a physician or other licensed practitioner of the healing arts within the scope of their practice under State law, for the maximum reduction of physical or mental disability and restoration of an individual to the best possible functional level;

(14) inpatient hospital services and nursing facility services for individuals 65 years of age or over in an institution for mental diseases;

(15) services in an intermediate care facility for the mentally retarded (other than in an institution for mental diseases) for individuals who are determined, in accordance with section 1396a(a)(31) of this title, to be in need of such care;

(16) effective January 1, 1973, inpatient psychiatric hospital services for individuals under age 21, as defined in subsection (h) of this section;

(17) services furnished by a nurse-midwife (as defined in section 1395x(gg) of this title) which the nurse-midwife is legally authorized to perform under State law (or the State regulatory mechanism provided by State law), whether or not the nurse-midwife is under the super-vision of, or associated with, a physician or other health care provider, and without regard to whether or not the services are performed in the area of management of the care of mothers and babies throughout the maternity cycle;

(18) hospice care (as defined in subsection (o) of this section);

(19) case-management services (as defined in section 1396n(g)(2) of this title) and TB-related services described in section 1396a(z)(2)(F) of this title;

(20) respiratory care services (as defined in section 1396a(e)(9)(C) of this title);

(21) services furnished by a certified pediatric nurse practitioner or certified family nurse practitioner (as defined by the Secretary) which the certified pediatric nurse practitioner or certified family nurse practitioner is legally authorized to perform under State law (or the State regulatory mechanism provided by State law), whether or not the certified pediatric nurse practitioner or certified family nurse practitioner is under the super-

vision of, or associated with, a physician or other health care provider;

(22) home and community care (to the extent allowed and as defined in section 1396t of this title) for functionally disabled elderly individuals; and

(23) community supported living arrangements services (to the extent allowed and as defined in section 1396u of this title);

(24) personal care services furnished to an individual who is not an inpatient or resident of a hospital, nursing facility, intermediate care facility for the mentally retarded, or institution for mental disease that are (A) authorized for the individual by a physician in accordance with a plan of treatment or (at the option of the State) otherwise authorized for the individual in accordance with a service plan approved by the State, (B) provided by an individual who is qualified to provide such services and who is not a member of the individual's family, and (C) furnished in a home or other location;

(25) primary care case management services (as defined in subsection (t) of this section);

(26) services furnished under a PACE program under section 1396u-4 of this title to PACE program eligible individuals enrolled under the program under such section; and

(27) any other medical care, and any other type of remedial care recognized under State law, specified by the Secretary,

except as otherwise provided in paragraph (16), such term does not include—

(A) any such payments with respect to care or services for any individual who is an inmate of a public

institution (except as a patient in a medical institution); or

(B) any such payments with respect to care or services for any individual who has not attained 65 years of age and who is a patient in an institution for mental diseases.

For purposes of clause (vi) of the preceding sentence, a person shall be considered essential to another individual if such person is the spouse of and is living with such individual, the needs of such person are taken into account in determining the amount of aid or assistance furnished to such individual (under a State plan approved under subchapter I, X, XIV, or XVI of this chapter), and such person is determined, under such a State plan, to be essential to the well-being of such individual. The payment described in the first sentence may include expenditures for medicare cost-sharing and for premiums under part B of subchapter XVIII of this chapter for individuals who are eligible for medical assistance under the plan and

(A) are receiving aid or assistance under any plan of the State approved under subchapters I, X, XIV, or XVI of this chapter, or part A of subchapter IV of this chapter, or with respect to whom supplemental security income benefits are being paid under subchapter XVI of this chapter, or

(B) with respect to whom there is being paid a State supplementary payment and are eligible for medical assistance equal in amount, duration, and scope to the medical assistance made available to individuals described in section 1396a(a)(10)(A) of this title, and, except in the case of individuals 65 years of age or older and disabled individuals entitled to health insurance benefits under subchapter XVIII of this chapter who are not enrolled under part B of subchapter XVIII of this chapter, other insurance premiums for medical or any other type of remedial care or the cost thereof. No

service (including counseling) shall be excluded from the definition of "medical assistance" solely because it is provided as a treatment service for alcoholism or drug dependency.

* * * *

42 USCA § 1396r-8: Payment for covered outpatient drugs

* * * *

(g) Drug use review

(1) In general

(A) In order to meet the requirement of section 1396b(i)(10)(B) of this title, a State shall provide, by not later than January 1, 1993, for a drug use review program described in paragraph (2) for covered outpatient drugs in order to assure that prescriptions (i) are appropriate, (ii) are medically necessary, and (iii) are not likely to result in adverse medical results. The program shall be designed to educate physicians and pharmacists to identify and reduce the frequency of patterns of fraud, abuse, gross overuse, or inappropriate or medically unnecessary care, among physicians, pharmacists, and patients, or associated with specific drugs or groups of drugs, as well as potential and actual severe adverse reactions to drugs including education on therapeutic appropriateness, overutilization and underutilization, appropriate use of generic products, therapeutic duplication, drug-disease contraindications, drug-drug interactions, incorrect drug dosage or duration of drug treatment, drug-allergy interactions, and clinical abuse/misuse.

(B) The program shall assess data on drug use against predetermined standards, consistent with the following:

(i) compendia which shall consist of the following:

(I) American Hospital Formulary Service Drug Information;

(II) United States Pharmacopeia-Drug Information;

(III) the DRUGDEX Information System; and

(IV) American Medical Association Drug Evaluations; and

(ii) the peer-reviewed medical literature.

(C) The Secretary, under the procedures established in section 1396b of this title, shall pay to each State an amount equal to 75 per centum of so much of the sums expended by the State plan during calendar years 1991 through 1993 as the Secretary determines is attributable to the statewide adoption of a drug use review program which conforms to the requirements of this subsection.

(D) States shall not be required to perform additional drug use reviews with respect to drugs dispensed to residents of nursing facilities which are in compliance with the drug regimen review procedures prescribed by the Secretary for such facilities in regulations implementing section 1396r of this title, currently at section 483.60 of title 42, Code of Federal Regulations.

(2) Description of program

Each drug use review program shall meet the following requirements for covered outpatient drugs:

(A) Prospective drug review

(i) The State plan shall provide for a review of drug therapy before each prescription is filled or delivered to an individual receiving benefits under this subchapter, typically at the point-of-sale or point of distribution. The review shall include

screening for potential drug therapy problems due to therapeutic duplication, drug-disease contraindications, drug-drug interactions (including serious interactions with nonprescription or over- the-counter drugs), incorrect drug dosage or duration of drug treatment, drug-allergy interactions, and clinical abuse/misuse. Each State shall use the compendia and literature referred to in paragraph (1)(B) as its source of standards for such review.

(ii) As part of the State's prospective drug use review program under this subparagraph applicable State law shall establish standards for counseling of individuals receiving benefits under this subchapter by pharmacists which includes at least the following:

(I) The pharmacist must offer to discuss with each individual receiving benefits under this subchapter or caregiver of such individual (in person, whenever practicable, or through access to a telephone service which is toll-free for long-distance calls) who presents a prescription, matters which in the exercise of the pharmacist's professional judgment (consistent with State law respecting the provision of such information), the pharmacist deems significant including the following:

(aa) The name and description of the medication.

(bb) The route, dosage form, dosage, route of administration, and duration of drug therapy.

(cc) Special directions and precautions for preparation, administration and use by the patient.

(dd) Common severe side or adverse effects or interactions and therapeutic contraindications that may be encountered, including their avoidance, and the action required if they occur.

(ee) Techniques for self-monitoring drug therapy.

(ff) Proper storage.

(gg) Prescription refill information.

(hh) Action to be taken in the event of a missed dose.

(II) A reasonable effort must be made by the pharmacist to obtain, record, and maintain at least the following information regarding individuals receiving benefits under this subchapter:

(aa) Name, address, telephone number, date of birth (or age) and gender.

(bb) Individual history where significant, including disease state or states, known allergies and drug reactions, and a comprehensive list of medications and relevant devices.

(cc) Pharmacist comments relevant to the individual's drug therapy.

Nothing in this clause shall be construed as requiring a pharmacist to provide consultation when an individual receiving benefits under this subchapter or caregiver of such individual refuses such consultation.

(B) Retrospective drug use review

The program shall provide, through its mechanized drug claims processing and information retrieval systems (approved by the Secretary under section 1396b(r) of this title) or otherwise, for the ongoing periodic examination of claims data and other records in order to identify patterns of fraud, abuse, gross overuse, or inappropriate or medically unnecessary care, among physicians, pharmacists and individuals receiving benefits under this subchapter, or associated with specific drugs or groups of drugs.

(C) Application of standards

The program shall, on an ongoing basis, assess data on drug use against explicit predetermined standards (using the compendia and literature referred to in subsection[3] (1)(B) as the source of standards for such assessment) including but not limited to monitoring for therapeutic appropriateness, overutilization and underutilization, appropriate use of generic products, therapeutic duplication, drug-disease contraindications, drug-drug interactions, incorrect drug dosage or duration of drug treatment, and clinical abuse/misuse and, as necessary, introduce remedial strategies, in order to improve the quality of care and to conserve program funds or personal expenditures.

(D) Educational program

The program shall, through its State drug use review board established under paragraph (3), either directly or through contracts with accredited health care educational institutions, State medical societies or State pharmacists associations/societies or other organizations as specified by the State, and using data

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[3] So in original. Probably should be "paragraph."

provided by the State drug use review board on common drug therapy problems, provide for active and ongoing educational outreach programs (including the activities described in paragraph (3)(C)(iii) of this subsection) to educate practitioners on common drug therapy problems with the aim of improving prescribing or dispensing practices.

(3) State drug use review board

(A) Establishment

Each State shall provide for the establishment of a drug use review board (hereinafter referred to as the "DUR Board") either directly or through a contract with a private organization.

(B) Membership

The membership of the DUR Board shall include health care professionals who have recognized knowledge and expertise in one or more of the following:

(i) The clinically appropriate prescribing of covered outpatient drugs.

(ii) The clinically appropriate dispensing and monitoring of covered outpatient drugs.

(iii) Drug use review, evaluation, and intervention.

(iv) Medical quality assurance.

The membership of the DUR Board shall be made up at least 1/3 but no more than 51 percent licensed and actively practicing physicians and at least 1/3 * * *[4] licensed and actively practicing pharmacists.

[4] So in original.

(C) Activities

The activities of the DUR Board shall include but not be limited to the following:

(i) Retrospective DUR as defined in section[5] (2)(B).

(ii) Application of standards as defined in section (2)(C).

(iii) Ongoing interventions for physicians and pharmacists, targeted toward therapy problems or individuals identified in the course of retrospective drug use reviews performed under this subsection. Intervention programs shall include, in appropriate instances, at least:

(I) information dissemination sufficient to ensure the ready availability to physicians and pharmacists in the State of information concerning its duties, powers, and basis for its standards;

(II) written, oral, or electronic reminders containing patient-specific or drug-specific (or both) information and suggested changes in prescribing or dispensing practices, communicated in a manner designed to ensure the privacy of patient-related information;

(III) use of face-to-face discussions between health care professionals who are experts in rational drug therapy and selected prescribers and pharmacists who have been targeted for educational intervention, including discussion of optimal prescribing, dispensing, or pharmacy care practices, and follow-up face-to-face discussions; and

[5] So in original. Probably should be "paragraph."

(IV) intensified review or monitoring of selected prescribers or dispensers.

The Board shall re-evaluate interventions after an appropriate period of time to determine if the intervention improved the quality of drug therapy, to evaluate the success of the interventions and make modifications as necessary.

(D) Annual report

Each State shall require the DUR Board to prepare a report on an annual basis. The State shall submit a report on an annual basis to the Secretary which shall include a description of the activities of the Board, including the nature and scope of the prospective and retrospective drug use review programs, a summary of the interventions used, an assessment of the impact of these educational interventions on quality of care, and an estimate of the cost savings generated as a result of such program. The Secretary shall utilize such report in evaluating the effectiveness of each State's drug use review program.

* * * *

October 5, 2000

TO: Interested Parties

FROM: /s/Christine Zukas-Lessard/s/, Acting Director, Bureau of Medical Services

SUBJECT: Proposed Rule: Chapter II and Chapter III Section 80, Pharmacy Services, of the Maine Medical Assistance Manual.

Attached, please find a copy of the proposed rules, Chapter II and Chapter III Section 80, Pharmacy Services, of the Maine Medical Assistance Manual.

Revisions to this rule include, but are not limited to, allowing out of state pharmacies to provide certain drugs, requirement of prior authorization consistent with medical necessity for drugs of manufacturers who do not participate in the Maine Rx Program, reduction in maximum supply of non-generic drugs to 34 days, clarification of certain drug coverage provisions, elimination of outdated appendices and elimination of chapter III.

A concise summary of the proposed rule is provided in the Notice of Rulemaking attached to this memo. This notice also provides information regarding the rule-making process. Please address all comments to the agency contact person identified in the attached notice.

Attachment

NOTICE OF AGENCY RULE-MAKING PROPOSAL

AGENCY: Department of Human Services, Bureau of Medical Services

RULE TITLE OR SUBJECT: Chapters II & III, Section 80, Pharmacy Services.

PROPOSED RULE NUMBER:

CONCISE SUMMARY:

Revisions to this rule include, but are not limited to, allowing out of state pharmacies to provide certain drugs, requirement of prior authorization consistent with medical necessity for drugs of manufacturers who do not participate in the Maine Rx Program, reduction in maximum supply of non-generic drugs to 34 days, clarification of certain drug coverage provisions, elimination of outdated appendices and elimination of chapter III.

THIS RULE WILL __ WILL NOT _X_ HAVE A FISCAL IMPACT ON MUNICIPALITIES.

STATUTORY AUTHORITY: 22 M.R.S.A., § 42, § 3173

PUBLIC HEARING:

November 8, 2000 at 3:00 p.m., Kennebec-Penobscot Room, Augusta Civic Center, 76 Community Drive, Augusta, Maine 04330

DEADLINE FOR COMMENTS: November 20, 2000

AGENCY CONTACT PERSON: Marianne Ringel, Comprehensive Health Planner

AGENCY NAME: Policy Development Unit, Bureau of Medical Services

ADDRESS: 11 State House Station
35 Anthony Avenue
Augusta, Maine 04333

TELEPHONE: 207-624-5518
TTY: 1-800-423-4331 or 207-287-1828 (Deaf/Hard of Hearing)

PLEASE APPROVE BOTTOM PORTION OF THIS FORM AND ASSIGN APPROPRIATE MFASIS NUMBER

APPROVED FOR PAYMENT /s/ Marianne Ringel
Authorized Signature

DATE: 10/10/00

FUND	AGENCY	ORG	APP	JOB	OBJT	AMOUNT
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80.01 DEFINITIONS

80.01-1 *Brand-name drug* is defined as a single-source drug, a cross-licensed drug or an innovator drug for which a lower-cost generic equivalent is *not* available.

80.01-2 *Compound Prescription* is any product for which two or more ingredients are extemporaneously mixed in usually accepted therapeutic doses. This requires the pharmacist's skill in weighing, measuring, levigating, etc., at the time of dispensing. The allowable compounding fee applies to the preparation of an individual prescription. It does not apply to prescriptions dispensed from a previously prepared stock supply (i.e.: premixaking a special lotion or ointment in gallons or pounds).

80.01-3 *Controlled Substances* are drugs that come within the scope of the Controlled Substances Act and are divided into five schedules—I, II, III, IV, V.

80.01-4 *Covered Services* are those medically necessary services for which payment can be made under Title XIX by the Department of Human Services.

80.01-5 *Dispensing Practitioner* is a licensed practitioner who, within the scope of his or her license, prepares and dispenses medication, instructs patients to self-administer medication on a regular basis, and is located no less than fifteen miles from a licensed pharmacy.

80.01-6 *Drug Utilization Review* (DUR) means a process designed to ensure that prescriptions shall be appropriate, medically necessary and not likely to result in adverse medical results.

80.01-7 *Drug Utilization Review Committee ~~Board~~* (DUR Committee ~~BOARD~~) means an advisory ~~board~~ committee to the State's Medicaid program, comprised of physicians and pharmacists who are licensed to prescribe or dispense drugs in Maine, ~~to the State's Medicaid program~~.

80.01-8 *Estimated Acquisition Cost* (EAC) is average wholesale price (AWP) minus ten_percent (10%).

80.01-9 *Formulary* is a list of medicines that includes all Legend (prescription) Drugs, to comply with OBRA 90 as amended, except those excluded by these regulations and those over-the-counter drugs listed in Section 80.05-1.

80.01-10 *Generic Drugs* are drugs other than those defined as brand.

80.01-11 *Legend Drug* is a drug bearing the statement "CAUTION: Federal Law Prohibits Dispensing Without A Prescription".

80.01-12 *Maine Maximum Allowable Cost* (MMAC) is the maximum cost allowed by the Maine Department of Human Services for certain multiple source drugs.

80.01-13 *Maximum Allowable Charge* (MAC) is the Federal Uupper Llimit (FUL) established by the federal government for certain prescription drugs. The Medicaid Program reimbursement to a pharmacy may not exceed the MAC for any such drugs.

80.01-14 *New Drugs* are drugs that receive an New Drug Application (NDA) from the Food and Drug Administration after November 1, 1990.

80.01-15 *OBRA 90* Omnibus Budget Reconciliation Act Of 1990 as amended.

80.01-16 *Over-The-Counter Drug* (OTC) is a drug that can be purchased without a prescription.

80.01-17 *Pharmacy Provider* is, for the purposes of determining the proper reimbursement charge, a corporation, association, partnership, or individual that either provides services pursuant to a provider agreement or is related by ownership or control to an entity that provides Medicaid services. This definition of Provider applies only to Section 80, Pharmacy Services, in the Maine Medical Assistance Manual.

80.01-18 *Retail Pharmacy* is a pharmacy which possesses a valid out-patient pharmacy license issued by the Commission of Pharmacy, and which serves Medicaid recipients.

80.01-19 *Usual & Customary Charge* is the reimbursement amount the general public is requested to pay for the goods or services provided.

80.02 ELIGIBILITY FOR CARE

The following recipients are eligible for covered services as set forth in this manual:

A. Categorically Needy Medicaid recipients, whose eligibility is shown on the Medical Eligibility Card as MM, and

B. Medically Needy Medicaid recipients, whose eligibility is shown on the Medical Eligibility Card as MI.

80.03 DURATION OF CARE

Each Title XIX and XXI recipient is eligible for as many covered services as are medically necessary. The

Department reserves the right to request additional information to evaluate medical necessity.

80.04 FORMULARY COMMITTEE

80.04-1 *Purpose*

The purpose of the Formulary Committee, if initiated, will be to establish a formulary for the Maine Medical Assistance Program to identify which prescription and over-the-counter drugs are subject to coverage under the Medicaid Program in compliance with OBRA 90 as amended. The statutory authority to establish a Formulary Committee is found at 22 M.R.S.A. 3174-M.

80.04-2 *Membership*

The Formulary Committee will be appointed by the Director of the Bureau of Medical Services. The committee shall consist of nine members, including three actively practicing pharmacists and three actively practicing physicians. At least one pharmacist shall be a clinical hospital pharmacist. At least one physician shall be a doctor who specializes in infectious diseases, one in primary care, and one in surgery. The pharmacists and physicians shall be Medicaid providers and shall serve for staggered three-year periods of time at the pleasure of the Director of the Bureau of Medical Services.

In addition to the members outlined above, the Director of the Bureau of Medical Services or the Director's designee, as well as the Pharmacy Programs Manager employed by the Bureau of Medical Services, and the Director of the Bureau of Health or the Director's

designee shall serve on the Committee. In addition to the nine voting members outlined above, the Formulary Committee will have at least two non-voting consumer members appointed by the Maine Medicaid Advisory Committee, who shall not be included when determining a two-thirds majority. The committee shall chose a chairperson from among the voting members. A secretary will be appointed by the Director of the Bureau of Medical Services.

80.04-3 *Meetings*

Meetings of the Drug Formulary Committee will be held at the discretion of the Director of the Bureau of Medical Services or the Committee Chairperson upon written petition of one-third of the Committee members.

80.04-4 *Approval of New Drugs*

Drugs will be added to the formulary, and will be deleted from the formulary, only upon a two-thirds vote of the Formulary Committee, the procedure for which is described in Section 80.04-5. When a new drug does not meet the two-thirds vote for approval to be added to the formulary, requests for such drugs shall be reviewed on an Authorization Prior to Provision (APTP) basis as outlined in Section 80.07-3.

80.04-5 *Formulary Policy and Procedures*

A. Drugs will be considered for addition to the formulary in one of four ways:

1. By the Formulary Committee, on the basis of evidence of sufficient requests for the drug through the APTP process

outlined in Section 80.07-3 to justify consideration for addition to the formulary. The Bureau of Medical Services may also request consideration of drugs based on the volume of inquiries received.

2. The Committee may initiate consideration of over-the-counter (OTC) drugs, since such drugs are not generally approved through the APTP process.

3. The Committee may also, through an on-going review of the formulary by therapeutic class, identify areas which are deficient or areas of possible deletion or restriction.

4. The drug manufacturer may initiate consideration of drugs for which there will be no fiscal impact as defined herein.

B. The steps to be followed for consideration by the Committee for the addition of drugs to the formulary is as follows:

1. The Ppharmacy Pprograms Mmanager will prepare material for distribution to Committee members commenting on efficacy, therapeutic benefits, and current peer reviewed literature.

   The Committee will arrange for specialty providers, as appropriate, to comment on this written material. The Ppharmacy Pprograms Mmanager shall classify the drug(s) under consideration into one of three categories, described below, which shall trigger a predetermined procedure. The Committee shall review that

determination and after review of the available material, may change the determination by a two-thirds majority vote of those members present.

Category A:

Therapeutic benefit and no projected fiscal impact. No therapeutic benefit and no projected fiscal impact.

Approval for drugs with no fiscal impact as defined herein shall be submitted to the next meeting of the Formulary Committee and shall be automatically recommended for addition to the formulary. No projected fiscal impact is defined as follows:

Reimbursement for the drug at the lowest adult daily dose for the primary indication will be compared to the average of the costs of the lowest adult daily dose for drugs within the same class, weighted by utilization for each drug within that class for the prior quarter. No consideration should be given to recommended course of therapy, improved, compliance, etc., for drugs in this category.

For combination drugs, the billed amount should be less than the combined prices of its components to have no fiscal impact.

Category B:

Therapeutic benefit and a projected fiscal impact.

Therapeutic benefit is defined as a clinically (not pharmacologically) more effective drug and/or a less toxic drug than alternative therapies currently on the formulary. A drug for which the sole advantage is convenience or compliance is not considered to have a therapeutic benefit.

Therapeutic benefit will be addressed by the clinician assigned the particular drug through his or her review with a final determination made by the Committee.

Drugs with an estimated fiscal impact shall normally be added to the formulary only in one of two ways:

a. a specific appropriation of funds from the legislature with approval of the Governor or

b. a deletion of other drugs forom the formulary to maintain budget neutrality.

The therapeutic benefit of the drug being considered should be weighed against the therapeutic benefit of drugs already on the formulary. If the value of the drug under consideration is not thought to be great enough to justify an offsetting deletion and if no funds are appropriated for the addition, the drug shall be put on a pending list of drugs to be added to the formulary once funds become available.

Category C:

No therapeutic benefit and a projected fiscal impact.

Drugs which are determined to be of no therapeutic benefit which have a projected fiscal impact shall not be added to the formulary. Such drugs would be available only through the APTP process to the extent necessary for a specific individual.

2. At the conclusion of discussion of all drugs being considered at a meeting, the Committee members shall record their vote for each drug on a form to be supplied at each meeting. The Chairperson will tally the votes and announce the Committee's preliminary determination. Written documentation of the vote will be kept on file at the Bureau of Medical Services.

3. The Department shall promulgate as a rule any additions or deletions to the formulary. After any hearing or comment period has expired, the Committee shall review any comments and take a final vote on the addition or deletion of any drugs. Any preliminary or final determination by the Committee requires a two-thirds majority vote of the members present. Inclusion of a drug on the formulary will automatically include all conventional dosage forms of that drug, with the exception of transdermal systems, sustained release and injectable dosage forms, unless specifically approved by The Formulary Committee.

4. All drugs added to the formulary will be referred to the Drug Utilization Review Committee (DUR) for monitoring.

80.05 COVERED SERVICES

80.05-1 *Drug Benefits*

Reimbursement is available for the following medically necessary drugs:

A. *Legend drugs.* All Llegend drugs found on the Maine Medical Assistance Program formulary, except those drugs set forth in Section 80.05-3, which must meet the requirements of APTP, and those drugs set forth in Section 80.05-4, which are covered for certain diagnoses only as set forth in that section. In addition, those legend drugs described as a non-covered service in Section 80.06 are not reimbursable.

B. *Over-the-Counter (OTC) drugs.* The following over-the-counter drugs and supplies when filled pursuant to a prescription:

Insulin, needles and syringes, urine or blood test strips* for diabetes, artificial tears or ophthalmic lubricants, oral iron for salts, calcium salts, except oyster shell source which is only covered for certain diagnoses (~~see~~See 80.05-54, G and F), diphenhydramine, quinine sulfate, nicotinic acid (niacin), meclizine, ~~and~~ permethrin, prenatal vitamins as described in (C) and smoking cessation aids.

* Strips used in conjunction with meters or electronic testing equipment are a Durable Medical Equipment item (Chapter II Section 60).

C. *Prenatal vitamins*, and OTC, prenatal vitamins for pregnancy and up to three months postpartum only and in quantities of one hundred only with no more than three refills. Reimbursement for prenatal vitamins is

usually for generic vitamins only. If the requesting physician wishes a particular brand, he or she must write "medically necessary" on the prescription.

D. Legend drugs that become available as over-the-counter drugs are eligible for reimbursement, by prescription only, if such coverage is cost effective and recommended for coverage by the Drug Utilization Review Committee, even if some brand name Products remain as Legend drugs.

~~D~~E. Reimbursement for drugs may be denied for the following reasons:

1. Utilization. If the Department in conjunction with the DUR board believes a drug is being generally overutilized or abused, it may choose to restrict that drug if other existing drugs are available to treat the problem.

2. Cost Containment. The Department may deny coverage for any drug that represents an excessive cost to the Medicaid program without correspondingly wide use by Medicaid recipients.

3. Cost Effectiveness. The Department may deny coverage for any drug if existing drugs available would treat the condition for less cost.

80.05-2. *Compound Prescriptions*

Reimbursement may be made for a compound prescription when the Department determines that the compound prescription contains at least one ingredient that is a legend drug, present in a therapeutic quantity, and

obtainable in effective strength only by prescription. A compound prescription which contains a laxative, stool softener, vitamin, antacid or cough and cold preparation and is prescribed solely to circumvent these Medicaid reimbursement limitations is not covered. Compound prescriptions containing a DESI drug (less than effective) are not covered. All active ~~ACTIVE~~ Ingredients contained in a compound prescription must be covered under ~~the R~~ a rebate ~~Program~~ agreement with the Maine Medicaid Program.

80.05-3. *Drug Utilization Review*

Drugs of manufacturers that do not participate in a rebate agreement for the Maine Rx program shall be reviewed by the Department as to the clinical appropriateness of prior authorization for those drugs under the Medicaid Program. Recommendations to prior authorize any of those drugs shall be referred to the Medicaid Drug Utilization Review Committee, for a final determination of whether those drugs should be prior authorized, in accordance with federal and state law. In all instances, Medicaid recipients shall be assured access to all medically necessary outpatient drugs.

80.05-~~4~~3. *Drugs That Require Authorization Prior to Provision (APTP)*

In addition to those drugs requiring prior authorization under Section 80.05-3, Tthe following drugs require APTP as described in Section 80.07-3 and must be supplied in the appropriate generic form if available:

A. Brand name controlled substance drugs listed on the Ffederal Uupper Llimits or MMAC list except for brand name methylphenidate, which only requires the physician to write "medically necessary" on the prescription. These drugs will only be approved for physician documented treatment failure.

B. Over-the-counter (OTC) drugs, including OTC vitamins and vitamin combinations, all OTC and legend laxatives and/or stool softeners. These items will be approved only when the prescriber can demonstrate, with supported medical justification, their cost effectiveness and that the use of these drugs is medically necessary for effective care of the patient. NOTE: These items are furnished by a nursing facility or ICF-MR and are included in the per diem rate of reimbursement for residents of these facilities.

C. Single entity dietary vitamins in prescription strengths only when used for a documented vitamin deficiency or prophylaxis to prevent such deficiency. Other uses, including but not limited to cosmetic purposes, are not a covered service. For the purposes of this section, vitamin K and dihydrotachysterol are not considered dietary vitamins.

D. The following drugs will be reimbursed only for the medical conditions described below. These will only be paid at the Medicaid Pharmacy rate using the NDC code and unit.

1. a. Total enteral nutrition to sustain the complete nutritional needs for recipients using nasogastric, gastrostomy or jejunostomy tubes.

b. Specified nutritional support products for patients who are:

~~i~~i. Currently malnourished: A Subjective Global Assessment (SGA) must be completed and submitted for risk assessment/documentation (see Appendix #3) before prior authorization can be considered.

~~ii~~ii. At significant risk for malnourishment secondary to an underlying medical condition. Documentation of medical condition must be submitted before prior authorization can be considered. A Subjective Global Assessment (SGA) may be requested.

Prior to consideration for authorization, the client's physician must supply the following additional documentation in writing: A description of the attempts made to employ other oral measures to correct the risk/condition; supplement used; time frame of use; reason for failure. Documentation that other oral measures are contraindicated and the reason why must also be submitted.

Prior authorization is effective for up to ~~six~~ twelve (12~~6~~) months as determined by medical criteria and documentation of ongoing medical necessity. ~~If use is required beyond six (6) months, updated medical documentation of ongoing medical necessity will again be required for prior authorization.~~

Medicaid will not cover specified nutritional support products as part or all of a voluntary weight loss program.

2. Lactulose, and its analogs, for recipients with portal encephalopathy or cirrhosis or as a laxative with written documentation from a physician of treatment failure with use of standard laxative therapy and demonstrated cost effectiveness.

3. ~~TB~~ Ddrugs for the treatment of tuberculosis when authorized by the Bureau of Health (see 80.06 (H)).

E. Drugs not found on the formulary or drugs not described as a covered service in Section 80.05 will be approved, in compliance with OBRA 90, only where no other drugs found on the formulary or otherwise reimbursed by the Maine Medicaid Program will adequately treat the condition presented or where only a new drug not found on the formulary will prevent a higher and more costly level of care.

F. Filling of Insulin syringes by Pharmacy Providers. This service will be approved only when the prescriber can demonstrate, with documented medical justification cost effectiveness and that the use of this service is medically necessary for effective care of the patient. (See 80.09(F)(1)(b)(iv)

G. Other Drugs. Additional drugs may be prior authorized as recommended by the Medicaid DUR Committee. Prescribers will be notified by quarterly mailings and the BMS website. In all instances Medicaid recipients shall be assured access to all medically necessary outpatient drugs.

80.05-54 *Drugs Covered for Certain Diagnoses Only*

Reimbursement for the following drugs will be made only for the conditions (diagnoses) described and only when the prescriber has written the diagnosis on the prescription. For a patient living in a nursing facility or an ICF-MR the diagnosis must only be noted in the patient's chart. To the extent that any of the drugs listed in this subsection (80.05-5) would require prior authorization under 80.05-43, such prior authorization is not necessary:

A. Methylphenidate and dextroamphetamine for attention deficit disorders or narcolepsy only.

B. Legend Cough & Cold Preparations and Decongestants for Sinusitis, Otitis Media, Emphysema or Asthma only.

C. B-12 for Documented Pernicious Anemia or Megaloblastic Anemia only.

D. Aspirin, Buffered Aspirin, Enteric Coated Aspirin and Acetaminophen for arthritis only and in quantities of 250, 500 or 1000 only.

E. Multi-vitamins and Vitamin E for cystic fibrosis.

F. The following oral drugs are covered for chronic renal failure, renal transplant recipients and dialysis:

Aluminum Carbonate Gel, Aluminum Hydroxide, Bisacodyl, B Vitamins with C, Calcium products including Calcium Oyster Shell, Calcitriol, Calcifediol, DHT (Dihydrotachysterol), Docusate Calcium, Docusate Sodium, Docusate w/Casanthranol, Ergocalciferol 50,000u, iron containing

products, Magaldrate; Multi-vitamins with 1mg. Folic Acid, Phosphorous replacement products, Psyllium Hydrophilic M ucilloid, Senna, Thiamin.

G. The following drugs are covered for recipients with quadriplegia and paraplegia:

Antacids, Ascorbic Acid, Bisacodyl, Calcium Oyster Shell, Docusate w/Casanthranol, Docusate Potassium, Docusate Sodium, Fleet Enemas, Glycerin Suppositories, Lubricating Jelly, Mineral Oil, Multivitamins, Povidone iodine gel, Psyllium Hydrophilic Mucilloid, Senna, Stress Vitamins, and Vitamin C & D.

~~The above drugs are not a Medicaid benefit under this Section in nursing facilities or ICFs MR if the produce is listed as part of the per diem rate of reimbursement in Chapter II, Section 67 "Nursing Facility Services" or as defined in Section 50.06-9 "ICF MR Services" or as defined in Section 60.04-4, "Medical Supplies and Durable Medical Equipment" of the Maine Agreement Manual or as defined in Attachments A or B of the Agreement between the Department and a Boarding Home.~~

80.06 NON-COVERED SERVICES

The following drugs are not reimbursed by the Medicaid Program:

A Anorexic, or certain weight loss drugs.

B Vitamins and vitamin combinations (except ~~generic~~ prenatal vitamins as allowed under 80.05-1(C) ~~during pregnancy and three months post partum~~ and vitamins covered for dialysis and recipients with quadriplegia and paraplegia or when the criteria in Section 80.05-3(B) and Section 80.05-4(E) is met).

C Laxatives and laxative combinations and stool softeners and stool softener combinations (except when the criteria in Section 80.05-3(B) is met.)

D Hexachlorophene scrubs for nursing facility patients.

E Products listed as part of the per diem rate of reimbursement in Chapter II, Section 67 "Nursing Facility Services" or as defined in Section 50.06-9 "ICF-MR Services" or as defined in Section 60.04-4, "Medical Supplies and Durable Medical Equipment" of the Maine Medical Assistance Manual or as defined in Attachments A or B of the Agreement between the Department and a residential care facility.

~~Needles and syringes for nursing home patients.~~

F Drugs discontinued or recalled by the manufacturers.

G Less than Effective Drugs as defined by the Food and Drug Administration (a list is available from the Bureau of Medical Services). These drugs are not covered under the Medicaid State plan, therefore, these drugs will not be deducted from a nursing facility resident's assessment.

H Drugs prescribed for TB (these are normally available from the Bureau of Health's Tuberculosis Program free of charge). Medicaid coverage is only available after referral from the Bureau of Health and Medicaid prior authorization.

I Legend drugs that become available as over-the-counter drugs are not eligible for reimbursement even if some brand name products remain as legend drugs.

J Over-the-counter drugs except drugs listed in 80.05-1(B) and when the criteria in Section 80.05-3 are ~~is~~ met.

K Any drug that is for experimental use or prescribed for indications other than those approved under OBRA 90 guidelines or have no Food and Drug Administration (FDA) sanctioned or approved indications.

L Drugs not covered under OBRA 90 as amended.

M Cosmetic agents. Ex.: Retin-A when used for wrinkles, Rogaine for hair growth.

N Drugs of manufacturers not participating in the Rebate Program.

O Fertility d~~D~~rugs.

P Nutritional support products as part or all of a voluntary weight loss program.

80.07 POLICIES AND PROCEDURES

80.07-1 *Regulation of Pricing*

Drugs added and deleted and price changes with regard to drugs which fall within the parameters of the Federal Upper Limits Program will be updated upon notification from the United States Government Health Care Financinge Administration.

Price changes with regard to drugs which fall within the MMAC guidelines and all other Medicaid drug benefits will be updated according to periodic ~~manual~~ review by the P~~p~~harmacy P~~p~~rograms M~~m~~anager of fluctuations in the average wholesale price list maintained by the Department of Human Services, Bureau of Medical Services under the guidelines of OBRA 90 as amended.

Designation of an effective date for all such changes will be determined together with allowance for mailing requirements in order to

afford a minimum thirty day notice to the provider.

80.07-2 *Standards of Participation*

A. A pharmacy provider must be duly licensed or certified by the appropriate regulatory body in the state in which it is located. An out-of-state provider may participate and receive payment for dispensed drugs only if the recipient has been injured or suffers a disease or illness while temporarily absent from Maine. The Maine Medicaid Program ~~State~~ will only reimburse drugs dispensed by out-of-state providers on an emergency basis. ~~Chronic or maintenance drugs are not a benefit in such cases.~~ Exceptions to this requirement are 1) for those out-of-state pharmacies located in towns within fifteen miles of the Maine-New Hampshire border, or five miles of the Maine-Canada border, that provide regular services to Maine recipients; ~~or~~ 2) those pharmacies which provide drugs for foster care children or other recipients that permanently reside in other states and are wards of the State of Maine; or 3) out of state pharmacies appropriately licensed or registered with the Maine Board of Pharmacy, satisfying prior authorization requirements and standards for quality of care to Medicaid beneficiaries as established by the Bureau of Medical Services and only for the provision of the following specialty medications:

1. Growth hormones
2. Antihemophilic factors
3. Intravenous Immune Globulin drugs (IVIG)

4. Drugs for the prevention of Respiratory Syncitial Virus (RSV)
5. Miscellaneous drugs not subject to the OBRA 90 rebate program requirements as authorized by the Bureau.

B. ~~Effective May 31, 1991, a~~A pharmacy provider will receive reimbursement only for drugs supplied by manufacturers who comply with the rebate requirements of the Health Care Financinge Administration in accordance with ~~the Omnibus Budget Reconciliation Act of 1990~~ (OBRA '90). If a pharmacy does not have a drug available that is provided by a manufacturer/labeler who complies with the rebate requirement of HCFA in conformance with OBRA 90, the pharmacist must directly and individually inform the individual of other pharmacies that may carry the drug. Additionally, drugs that are otherwise covered by Medicaid but are provided from manufacturers/labelers not covered under the rebate agreement may be subject to prior authorization requirements upon thirty days written notice from the Bureau. (See 80.04-5 for prior authorization policy.)

~~B~~C. Any pharmacist or dispensing practitioner, whether in State or out of State, who wishes to submit claims for payment must submit an application for participation to the Bureau of Medical Services, Provider File Unit~~Division of Medical Claims Review~~. The Bureau will review the application and notify the submitting provider whether or not he or she is accepted as a provider and if accepted, the effective date. An application may be denied, terminated or not renewed for any of the

grounds set forth in Maine Medical Assistance Manual, Chapter I. An accepted application must be on file before any reimbursement for any item or service will be made.

80.07-3 *Authorization Prior to Provision (APTP)*

A. The procedure for all drugs requiring APTP is as follows:

All prior authorization requests shall be made in writing and include the following:

1. Recipient name, Medicaid identification number and birthdate.
2. Patient diagnosis, prognosis and other pertinent information.
3. List of other drugs currently prescribed for the patient.
4. Name of drug(s) requested, the National Drug Code (NDC), and the medical justification for the request, including the reasons why other reimbursable drugs are not adequate to treat the condition presented.
5. Requesting prescriber's name, address, signature and telephone number.
6. Name and address of pharmacy where drug(s) are to be obtained.
7. Requests for APTP must be sent to: Pharmacy~~Drug~~ Program Coordinator, 11 State House Station, Augusta, Maine 04333-0011.
8. When the request is received, it will be reviewed and a determination

made concerning whether or not the drug will be added as a limited benefit for the recipient according to the standards set forth in Section 80.05-3. A completed prior authorization request will be responded to within 24 hours. If a request is approved, it is valid for a maximum of one year, at which time a new prior authorization is required.

Prior authorization shall be given retroactively if it is determined by the prescriber that an emergency requires that the drug be dispensed immediately for the patient's well being. However, the Bureau's Pharmacy Programs Manager or his or her representative must be contacted at 287-1818, or 1-800-321-5557 for a verbal authorization.

If not available at that time, the Pharmacy Programs Manager or his or her representative ~~MUST BE CONTACTED ON THE FIRST WORKING DAY THEREAFTER~~ must be contacted on the first working day thereafter.

Following any verbal authorization, the prescriber must make the request in writing and must include a description and justification of the emergency, following the procedure discussed above and the standards set forth in Section Reimbursement for such drugs. shall continue pending written Departmental action.

80.07-4 *Weekend and Holiday Authorization Prior to Provision*

A. When a drug requires APTP and the Bureau of Medical Services is closed, a pharmacist or dispensing practitioner may request APTP by

contacting the agent authorized by the Bureau of Medical Services. The staff shall review and respond to APTP requests and provide verbal approval when appropriate. Any APTP requests for recipients whose medical needs cannot wait until the Bureau of Medical Services' offices are open, shall be made by calling the authorized agent.

NOTE: list of authorized agents will be provided by the Bureau of Medical Services.

B. All APTP requests made after 3:00 PM the day before the Bureau of Medical Services' offices are closed and before 8:00 AM the day the Bureau of Medical Services' office reopens,' shall be responded to by the authorized agent. All APTP requests that receive verbal approval shall be followed with written documentation, as defined in Section 80.07, from the prescriber within seven (7) days from the date of verbal approval. All written documentation shall be submitted to:

Pharmacy~~Drug~~ Program Coordinator
Bureau of Medical Services
~~Professional Claims Review Unit~~
11 State House Station /249 Western Ave.
Augusta, Maine 04333-0011
- OR - fax 28~~7~~-8601~~2675~~

C. All non-immediate APTP requests shall be submitted to the address listed above.~~:~~

~~Drug Program Coordinator~~
~~Bureau of Medical Services~~
~~Professional Claims Review Unit~~
~~11 State House Station /249 Western Ave.~~
~~Augusta, Maine 04333-0011~~
~~- OR - fax 287-2675~~

~~C~~D. Only when the prescriber is unable to reach the ~~State~~Bureau of Medical Services or the authorized agent for prior authorization, a minimum of a 72-hour supply shall be provided to the recipient except for controlled substances, brand named MAC drugs, and any drug that cannot be reimbursed under existing State and Federal Regulations.

80.07-5 *Dispensing Practices*

Compliance with the following dispensing policies is required:

A. Dispensing practices must be in accordance with the best medical, pharmaceutical and economical practice.

B. Generic drugs as rated A in the current edition of the FDA Orange Book must be dispensed in accordance with State law, if available at a lower cost than the brand name product, unless the practitioner writes the words "Medically Necessary" in his/her own handwriting on the face of the prescription or the prescriber's order sheet for institutionalized patients. Nothing other than the prescriber's own handwritten statement is acceptable. The printed box on the form or order form that could be checked by the prescriber to indicate that a name brand is necessary is not acceptable. (See 80.09-E)

C. Single source or co-licensed d~~D~~rugs must be dispensed in quantities not to exceed a 34 day supply. FDA A-rated generic drugs must be dispensed in quantities sufficient to effect optimum economy (normally not less than a one-month supply nor more than a three-month supply for maintenance medications for

chronic illness). ~~Pharmacist~~Providers will not be reimbursed for split prescriptions. Also see 80.09-(C).

D. For the classes of maintenance therapy listed below, a minimum of one month's (thirty days) supply must be supplied except when the prescriber's written orders are to the contrary or it is the initial filling of the prescription. Drugs in ointment or cream form must be dispensed in the largest tube available when used for maintenance therapy, except in the initial filling of the prescription.

1. Analgesics
2. Antianemia drugs
3. Anti-emetics
4. Antihistamines
5. Barbiturates
6. Cardiovascular drugs
7. Dermatologicals
8. Diuretics
9. Hormones
10. Hypnotics
11. Psychotherapeutic agents
12. Sedatives
13. Spasmolytics
14. Sulfonamides
15. Hypertensive drugs
16. Tranquilizers
17. Drugs for Parkinson's disease

18. Anti-epileptic drugs
19. Peripheral vasodilators
20. Antiarthritic drugs

E. All prescriptions must be dispensed within thirty days of the date prescribed.

F. Payment for medications dispensed in quantities in lesser or greater amounts than therapeutically reasonable may be withheld pending contact with the prescriber to determine justification for the amount.

G. All prenatal vitamins must be dispensed in quantities of one hundred with no more than three refills.

H. Aspirin and acetaminophen must be dispensed in quantities of 250, 500 or 1000 only.

I. ~~*Pharmacis Affiliated with Hospitals, Boarding Homes and/or Nursing Homes.*~~

A pharmacy affiliated through common ownership or control with a hospital, ~~boarding~~ home, ICF-MR, private nonmedical institution, residential care facility and/or nursing home is allowed to dispense Medicaid covered ~~Medicaid~~ prescription drugs to Medicaid recipients in that facility. The drugs must be dispensed by a registered pharmacist, according to dispensing regulations. Drugs are to be billed in a manner consistent with the Department's billing guidelines and drug claim processing system (see Section 80.09) without professional fee.

J. ~~*Dispensing Practitioners*~~

Practitioners who have been authorized to dispense drugs for Medicaid patients shall not

receive a dispensing fee, but will be allowed to charge the co-pay amount in addition to the acquisition cost of drugs dispensed. Records of all such dispensing must be available for review and audit.

A participating pharmacist must maintain the original copy of all prescriptions for which payment from the Medical Assistance Program is requested. The original prescription shall be either a hard copy generated by a computer, written by the prescriber, or reduced to writing when received by the pharmacist by telephone. Information required by the Maine State Board of Pharmacy shall be recorded on each prescription and must include name of patient, name of drug, quantity ordered, directions, name of prescriber, date written and initials of pharmacist filling prescription. A record of each refill must be kept on the prescription or on the profile or be available on a computer.

80.07-6 *Refills*

Reimbursement for refills will be made only if the following conditions are met:

A. The prescription authorizes refills.

B. No more than one year has passed since the date of the original issue. Reimbursement for a drug later than one year from the date of original issue requires a new prescription, subject to the limitations described in Section 80, Pharmacy Services, subsection 80.07-5 Dispensing Practices.

C. Reimbursement will be made for refills dispensed in no less than a thirty-day supply

for chronic conditions except when the prescriber specifically directs otherwise.

D. ~~Reimbursement will not be made for amounts dispensed in more that a thirty-day supply~~ Single source or co-licensed drugs must be dispensed in quantities not to exceed a 34-day supply. FDA A-rated generic drugs must be dispensed in quantities sufficient to effect optimum economy (normally not less than a one-month supply nor more than a three-month supply for maintenance medications for chronic illness). Providers will not be reimbursed for split prescriptions. ~~(except for chronic illness) unless the recipient will be out of state and will not return before a refill is needed~~. See section 80.07-5(c).

E. Refills shall be mailed to the recipient upon request.

80.07-7 *Pharmacist's Responsibility*

The Department supports generally-accepted professional judgments made by pharmacists, including the right to refuse to dispense any prescription which appears to be improperly executed or unsafe, based on the pharmacist's professional judgment. The Department expects that any pharmacist who suspects that a recipient may be inappropriately using a drug will report the recipient to the Pharmacy Programs Manager or to the Director, Surveillance and Utilization Review Unit, Bureau of Medical Services, 11 State House Station, 35 Anthony Ave., Augusta, Maine 04333-0011.

80.07-8 *Recipient Restriction Program*

One of the purposes of the Recipient Restriction Program (See Chapter IV in this Manual) is to decrease and control over-utilization or abuse of Medicaid reimbursed services and benefits and to minimize medically unnecessary and potentially addictive drug use.

Restricted recipients are issued Medical eligibility cards that identify their authorized health care providers. Providers not listed on the cards will not be reimbursed for their services unless they were furnished in emergencies or with prior approval from the Division of Surveillance and Utilization Review.

For additional information, please see Chapter IV, Recipient Restriction Program. ~~and Chapter II Section 80.07 of the Maine Medical Assistance Manual.~~

A recipient may appeal a decision concerning this program to the Commissioner of the Department of Human Services in accordance with appeal procedures described in Chapter I of the Maine Medical Assistance Manual.

80.07-9 *Surveillance and Utilization Review*

Surveillance and Utilization review requirements are delineated in Chapter I of the Maine Medical Assistance Manual.

~~A. The Division of Surveillance and Utilization Review monitors the medical services provided and determines the appropriateness and necessity of the services.~~

~~B. The Department and its professional advisors regard the maintenance of adequate treatment and service records as essential in substantiating the delivery of quality care. In addition, providers should be aware that treatment and service records are key documents used for post-payment reviews. In the absence of proper and complete records, no payment will be made and payments previously made may be recovered in accordance with Chapter I of the Maine Medical Assistan e Manual.~~

~~C. Upon request, the provider must furnish to the Department, without additional charge, the records, or copies therof, corresponding to and substantiating services billed by that provider.~~

~~D. The Department expects that records or other pertinent information will be transferred, upon request and with the patient's signed release of information, to other clinicians involved in the patient's care.~~

80.08 CO-PAYMENT

A. A co-payment is to be charged by the pharmacy to each Medicaid recipient for each prescription filled or refilled except as specified in Section 80.08-2. The amount of the co-payment shall not exceed $2 per generic drug and $3 per brand-name drug according to the following schedule:

Medicaid Payment for Rx		*Recipient Co-payment*
$10.00 or less		$ .50
$10.01 -25.00		$1.00
$25.01 - 50.00	for generic drugs	$2.00
$50.01 or more	for brand-name drugs	$3.00

B. No pharmacy may discount the co-payment for promotional purposes. The pharmacy shall not deny pharmacy services to a Medicaid recipient on account of the recipient's inability to pay a co-payment.

Providers must rely upon the recipient's representation that he or she does not have the cash available to pay the co-payment. However, the individual's inability to pay does not eliminate his or her liability for the co-payment.

C. If a recipient is dispensed a drug in a quantity specifically intended by the prescriber or pharmacist to last less than one month for the recipient's health and welfare, only one co-payment for that drug that month is required.

D. Copayment exemptions and dispute resolution procedures are described in Chapter I of the Maine Medical Assistance Manual.

~~80.08-2 *Co-payment Exemptions*~~

~~No co-payment may be imposed with respect to the following services:~~

~~A. Family planning services and supplies;~~

~~B. Services furnished to individuals under twenty-one (21) years of age;~~

~~C. Services furnished to individual who is an inpatient in a hospital, skilled nursing facility, nursing facility, ICF-MR or other medical institution, if that individual is required, as a condition of receiving services in that institution, to spend for costs of medical care all but a minimal amount of his or her income required for personal needs.~~

~~D. Services furnished to pregnant women, including services provided during the three months following the end of a pregnancy;~~

~~E. Emergency services, i.e., when failure to provide the service could reasonably be expected to:~~

~~1) place the recipient's health in serious jeopardy;~~

~~2) cause serious impairment to bodily functions, or~~

~~3) cause serious dysfunction of any bodily organ or part.~~

~~F. Services furnished to an individual of a health maintenance organization in which he or she is enrolled.~~

~~G. Recipients in State custody.~~

~~H. Services furnished to any individual who is a resident of a boarding home or a foster home;~~

~~Medicaid recipients exempt from co-payment requirements are identified by a "NO" in the co-payment column on the recipient's Medical Eligibility Card.~~

~~80.08-3 *Co-payment Limitation*~~

~~If a recipient is dispensed a drug in a quantity specifically intended by the prescriber or pharmacist to last less than one month for the recipient's health and welfare, only one co-payment for that drug that month is required.~~

~~80.08-4 *Co-payment Disputes*~~

~~If a recipient believes that he or she is exempt from a co-payment, disputes the amount of the co-payment, or has been denied a service for~~

~~failure to make a co-payment, he or she may contact the Department for assistance in resolving that dispute. Complaints should be directed to the Assistant Director, Bureau of Medical Services at 287-2674.~~

80.09 REIMBURSEMENT

Medicaid reimbursement for drugs covered under this Section will only be made for drugs of any manufacturer that has entered into and complies with a rebate agreement and specific reporting requirements as defined by Title 19 of the Social Security Act Section 1927 described in OBRA 90 as amended.

A. The amount of payment for services requested and rendered shall be the lowest of the following:

1. The usual and customary charge or any amount the provider will accept from any other third party program or from the public in the form of discounts, special rebates, incentives, coupons, club plans or contracts with the exception of senior citizen discounts; or
2. The estimated acquisition cost (EAC) plus $3.35 professional fee except as stated in Section 80.07(5)(I).
3. The Federal Upper Limit (FUL) or the Maine maximum allowable cost (MMAC) plus $3.35 professional fee except as stated in Section 80.07(5)(I).
4. Maximum reimbursement shall be at average wholesale price (AWP) minus seven and one-half percent (71/2%) for those pharmacies servicing nursing facilities, private non-medical institutions, ICFs-MR and residential care facility ~~boarding homes~~ for which the dispensing program bills Maine Medicaid for:

a. only the actual doses administered with one dispensing fee per drug per month; and

b. the program results in no drugs subject to return for credit as described in Section 80.09(H).

The co-payment specified in Chapter II, Section 80.08 "Co-payment" of the Maine Medical Assistance Manual will then be deducted from the amount reimbursed.

The Department will ~~periodically~~ notify pharmacies of updates to ~~publish a~~ lists of drugs and their prices covered by FUL or MMAC and a full copy can be provided upon request to the Bureau of Medical Services.

B In accordance with Chapter I, of the Maine Medical Assistance Manual, it is the responsibility of the provider to seek payment from every other source except the Low Cost Drugs for the Elderly Program (DEL).

It is the responsibility of the provider to verify a patient's eligibility for medical assistance prior to providing services by requesting the individual to present his or her Medical Eligibility Card on each occasion that a service is provided and verifying this information as described in Chapter 1 of the MMAM.

C. If a recipient's eligibility is due to expire within one month of the date of service, reimbursement will only be made for up to a one-month's supply.

D. State Maximum Allowable Cost (MMAC)

The establishment of a MMAC is subject, but not limited, to the following considerations:

1. Multiple manufacturers;

2. Broad wholesale price span;

3. Availability of drugs to retailers at the selected cost;

4. High volume of Medicaid recipient utilization;

5. Bioequivalence or interchangeability.

E. Reimbursement for Drugs More Expensive Than MAC or MMAC Allowances

A prescriber who requests a drug more expensive than a MAC or MMAC limited drug must certify its need in writing with the words "medically necessary" on the prescription or, for institutionalized patients, on the prescriber's orders. The printed box on the prescription blank that could be checked by the prescriber to indicate that a name brand is necessary is not acceptable. Nothing other than the prescriber's own handwritten statement on the prescription or the prescriber's order will be accepted.

Note: This does not apply to drugs more expensive than MAC, MMAC limited drugs that are controlled substances (Classes II, III, IV, V). For these drugs, prior authorization must be requested by the prescriber. The prescriber must submit objective medical evidence showing a treatment failure of the generic drug (See Section 80.05-3), except for Methylphenidate which only requires "Medically Necessary" in the physician's handwriting on the prescription.

F. Reimbursement for Compounded Drugs

Reimbursement for these drugs is determined by subtracting the co-payment described in Section 80.08, from the sum of the professional fee and the ingredient cost.

1. Professional fees for compound drugs are as follows:

a. Submitted by paper claim form:

(~~1~~i) $3.35 for an amount dispensed from a stock supply, or for solutions or lotions involving no weighing.

(~~2~~ii) $5.35 for compounding handmade suppositories, powder papers, capsules and tablet triturates and for mixing home TPN hyperalimentation.

(~~3~~iii) $4.35 for compounding ointments and for solutions or lotions involving weighing one or more ingredients and mixing home intravenous (IV) solutions.

b. Submitted electronically: **

(~~1~~i) $3.10 for an amount dispensed from a stock supply, or for solutions or lotions involving no weighing, for all claims electronically submitted for verification, eligibility, adjudication, ProDur edits, and payment.

(~~2~~ii) $5.10 for compounding handmade suppositories, powder papers, capsules and tablet triturates and for mixing home TPN hyperalimentation, for all claims electronically submitted for verification, eligibility, adjudication, ProDur edits, and payment.

(iii) $4.10 for compounding ointments and for solutions or lotions involving weighing one or more ingredients and mixing home intravenous (IV)

solutions, for all claims electronically submitted for verification, eligibility, adjudication, ProDur edits, and payment.

(iv) $12.50 for filling insulin syringes for a maximum 14-day supply for all claims electronically submitted for verification, eligibility, adjudication, ProDur edits, and payment.

** Effective with dates of service on or after *July 23, 1998*.

2. The ingredient cost is the sum of the cost of the defined ingredients contained in the compound drug. For any ingredients that cost twenty-five cents or less, twenty-five cents is the allowed charge.

G. Reimbursement for Prenatal Vitamins:

Reimbursement for prenatal vitamins is for generic vitamins only. If the requesting physician wishes a particular brand, he or she must write "medically necessary" on the prescription.

H. All drugs dispensed to patients in nursing facilities, ICFs-MR, and residential care facility ~~boarding homes~~ shall be dispensed in thirty-day supplies except for Schedule II narcotics not used for maintenance therapy. Schedule II items may be dispensed in lesser days supply if therapeutically and financially reasonable or to comply with the institution's stop order policies. Drugs in ointment form shall normally be dispensed in the largest size available.

1. All ~~FULL OR PARTIAL UNIT DOSE~~ full or partial unit dose or modified unit dose ~~MODIFIED UNIT DOSE~~ drugs except the

following shall be returned to the pharmacy for credit if they are in a reusable condition.

a. Liquids and ointments, unless sealed packages are unopened,

b. Class II controlled drugs.

2. Instructions for Return

a. Institutions will complete Pharmaceutical Control Sheet (MCMA 45) columns 1 through 7.

b. Institutions will distribute copies of the completed form in the following manner:

Send green and yellow sheets with listed medication to servicing pharmacy;

Retain blue sheet for nursing home files;

Return white copy to:

Drug Program Coordinator
Professional Claims Review Unit
11 State House, Station
Augusta, Maine 04333

c. Pharmacies will calculate the unit price and total value (columns 8 and 9), total each sheet, and return the green copy to the Drug Program Coordinator at the above address. The Department will total all sheets and charge back 70% of the value, allowing the servicing pharmacy 30% for work involved. These forms should be sent promptly and at least monthly. Medication not returned to a pharmacy for credit shall be destroyed in the nursing or boarding facility and witnessed by two persons who must then sign the MCMA 45.

80.010 BILLING INSTRUCTIONS

A. Manual ~~B~~billing must be accomplished in accordance with the Department's Billing requirements, per the "Billing Instructions for Pharmacy Services".

B. Electronic billing must be accomplished in accordance with the Department's billing requirements per the Electronic Media Claims rider to the provider enrollment agreement.

~~B. In order to receive full Medicaid reimbursement for claims submitted for a service that is defined as an exemption in Section 80.08-3 (Co-Pay Limitation), please use a "C" indicator in block 6 of the original claim form. A dash must be used to avoid keying errors (ex. 123456-C). On refill claim forms, please put a "C" after the Rx number.~~

October 5, 2000

TO: Interested Parties

FROM: /s/Christine Zukas-Lessard/s/, Acting Director, Bureau of Medical Services

SUBJECT: Proposed Rule: Rules of the Department of Human Services, Chapter 130, Section 1, Maine Rx Program.

Attached, please find a copy of the proposed rule, Chapter 130, Section 1, Maine Rx Program, of the Rules of the Department of Human Services.

This new rule implements the legislatively mandated Maine Rx Program. The program allows Maine residents enrolled in the Program to purchase drugs at reduced cost.

A concise summary of the proposed rule is provided in the Notice of Rulemaking attached to this memo. This notice also provides information regarding the rule-making process. Please address all comments to the agency contact person identified in the attached notice.

Attachment

NOTICE OF AGENCY RULE-MAKING PROPOSAL

AGENCY: Department of Human Services, Bureau of Medical Services

RULE TITLE OR SUBJECT: Rules of the Department of Human Services, Chapter 130, Section 1, Maine Rx Program

PROPOSED RULE NUMBER:

CONCISE SUMMARY:

This new rule implements the legislatively mandated Maine Rx Program. The program allows Maine residents enrolled in the Program to purchase drugs at reduced cost.

THIS RULE WILL ___ WILL NOT _X_ HAVE A FISCAL IMPACT ON MUNICIPALITIES.

STATUTORY AUTHORITY: 22 M.R.S.A., § 254-B

PUBLIC HEARING:

November 8, 2000 at 1:00 p.m., Kennebec-Penobscot Room, Augusta Civic Center, 76 Community Drive, Augusta, Maine 04330

DEADLINE FOR COMMENTS: November 20, 2000

AGENCY CONTACT PERSON: Marianne Ringel, Comprehensive Health Planner

AGENCY NAME: Policy Development Unit, Bureau of Medical Services

ADDRESS: 11 State House Station
35 Anthony Avenue
Augusta, Maine 04333

TELEPHONE: 207-624-5518
TTY: 1-800-423-4331
or 207-287-1828
(Deaf/Hard of Hearing)

PLEASE APPROVE BOTTOM PORTION OF THIS FORM AND ASSIGN APPROPRIATE MFASIS NUMBER

APPROVED FOR PAYMENT /s/
Authorized Signature

DATE: 10/10/00

FUND	AGENCY	ORG	APP	JOB	OBJT	AMOUNT
010	10A	3010	012			

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1. Authority

The Maine Rx Program is authorized by, and these regulations are issued under, the authority of 22 MRSA Chapter 603. The Commissioner of the Department of Human Services has delegated the responsibility for administration of the Program to the Bureau of Medical Services.

2. Definitions

Department means Department of Human Services.

Participating Pharmacy means a retail pharmacy located in this State, or another business licensed to dispense prescription drugs in this State, that has signed a Maine Rx Agreement.

Average Wholesale Price means the wholesale price charged on a specific commodity that is assigned by the drug manufacturer and is listed in a nationally recognized drug pricing file.

Labeler means an entity or person that receives prescription drugs from a manufacturer or wholesaler and repackages those drugs for later retail sale.

National Drug Code (NDC) is the identifying number maintained by the Food and Drug Administration.

3. Program Eligibility

In order to be eligible to participate in the Maine Rx Program, the participant must be a resident of the State of Maine. Under existing Maine Board of Pharmacy rules, a pharmacy must have a current address on file for a patient when a prescription is filled. For purposes of this Chapter, this existing record-keeping requirement verifies residency. Eligibility may be subject to verification through audit. Enrollment applications may be obtained at local DHS offices, town offices, hospitals,

health care providers, pharmacies and other designated locations.

4. Maine Rx Enrollment Card

Each eligible participant in the Maine Rx Program will be issued an eligibility card. The Department or its authorized agent will issue a permanent card to each enrollee in the Maine Rx Program. The permanent card will be issued by mail only to a Maine address.

5. Duration of Eligibility

Applicants remain eligible until the applicant is no longer a resident of the State of Maine. The enrollee is responsible for notifying the Department within 30 days of the event that makes him or her ineligible.

The Department reserves the right to deny to or terminate eligibility for individuals who engage in fraud or abuse.

There is no ceiling on frequency, total number, or cost of the prescriptions filled for an individual participant.

6. Appeal of Denial of Eligibility

Whenever an individual has been denied eligibility to this Program, or had his or her eligibility terminated he or she may appeal the decision pursuant to the Administrative Procedures Act as described in the member handbook.

7. Pharmacy Participation

A. Any pharmacy that wishes to submit claims for payment under the Maine Rx Program must be a pharmacy located in Maine, or another business licensed to dispense prescription drugs in this State.

B. An application for participation in the Maine Rx Program must be submitted and approved by the Department for all participating pharmacies.

C. Requirements for pharmacies that are approved for participation in the Program include, but are not limited to the following:

1. Immediate written notification to the Department of any change in any of the information which the pharmacy previously submitted to the Department;

2. Non-interference with the recipient's freedom of choice in seeking medical care or services from any institution, agency, pharmacy, or person who is qualified to perform a required service;

3. Provision of services and supplies to recipients in full compliance with Title VI of the Civil Rights Act of 1964, which prohibits discrimination on the grounds of race, color, or national origin, and also on the basis of religious beliefs, sex, or handicapping conditions;

4. Provision of services and supplies to recipients in this Program which are of the same quality and mode of delivery as are provided to the general public. Participating pharmacies are required to provide services and supplies to Program recipients from manufacturers who participate in the drug rebate program for the Maine Rx Program;

5. Maintenance and retention of business and professional records sufficient to document fully and accurately the nature, scope and details of the drugs and services provided. These records must be saved for five (5) years, or for a period of time not less than that required by the Health Care Financing Administration, whichever is less. However, if an audit is initiated within the required retention period, the records must be retained until the audit is completed;

6. Furnishing to the Department, in the form and manner requested, pertinent information regarding services for which charges are made;

7. Holding confidential, and using for authorized Program purposes only, all medical information; and

8. Compliance with the requirements of applicable Federal and State laws, including the provisions of the statute and regulations establishing this Program, and not engaging in a practice that is prohibited by applicable Federal and State laws, or Program regulations.

D. There shall be no cost imposed by the Department to the pharmacy for submitting claims or participating in this Program.

The pharmacy reserves the right to decline to dispense any prescription which appears to be improperly executed and/or which in the professional judgment of the pharmacist is unsafe as presented, or may be harmful if not monitored.

8. Termination of Pharmacy Participation

The participating pharmacy may terminate his or her participation in the Maine Rx Program at any time. Written notification of voluntary termination is to be made to the Bureau of Medical Services. A termination notice is effective when received by the Department. When a termination notice is sent to the pharmacy by the Department, it is effective thirty (30) days after receipt of the notice by the pharmacy.

9. Appeals

Any pharmacy that is aggrieved by a decision made pursuant to this policy has thirty (30) calendar days from the date of receipt of that decision to request an informal

review, in writing to the Director of the Bureau of Medical Services. This review will be conducted by the Director of the Bureau, or a designee who was not involved in the decision under review. A written report of the decision resulting from that review will be issued to the pharmacy.

If the pharmacy is dissatisfied with the informal review decision, an administrative hearing may be requested by writing to the Commissioner of the Department of Human Services within thirty (30) days from the date of receipt of the Director's report. The appeal process under the Maine Rx Program, for all pharmacy providers, whether or not participating in the Medicaid Program, is identical to the appeal process under the Maine Medicaid Program. See Chapter I of the Maine Medical Assistance Manual for more details on provider appeals.

10. Drugs Provided

A. Coverage and reimbursement under the Maine RX Program will only be made for drugs from those manufacturers or labelers with a signed Maine Rx rebate agreement with the Department. These drugs must be dispensed pursuant to a prescription although the medication may be available without a prescription.

B. Drug Rebate Program

1. No payment will be made for drugs of manufacturers or labelers that do not enter into a rebate agreement with the Department for drugs approved under the Program. The Department shall have drug rebate agreements with individual pharmaceutical manufacturers or labelers in amounts negotiated and agreed as between the Department and the manufacturer or labeler.

Each such agreement shall provide that the pharmaceutical manufacturer or labeler shall make quarterly rebate payments to the Department for the total number of dosage units of each form and strength of a prescription drug which the Department reports as reimbursed to providers of prescription drugs, provided such payments shall not be due until thirty (30) days following the manufacturer's receipt of utilization data from the Department including the number of dosage units reimbursed to pharmacies for prescription drugs during the period for which payment is due.

2. Upon receipt of such data from the Department, the pharmaceutical manufacturer or labeler shall calculate the quarterly payment. The Department may, at its expense, hire a mutually agreed upon independent auditor to verify the calculation and payment

In the event that a discrepancy is discovered between the pharmaceutical manufacturer's or labeler's calculation and the independent auditor's calculation, the pharmaceutical manufacturer or labeler shall justify its calculation or make payment to the Department for any additional amount due. The pharmaceutical manufacturer or labeler may, at its expense, hire a mutually agreed upon independent auditor to verify the accuracy of the utilization data provided by the Department.

In the event that a discrepancy is discovered, the Department shall justify its data or refund any excess payment to the pharmaceutical manufacturer or labeler.

3. Those prescription drugs of a pharmaceutical manufacturer or labeler that enters into an agreement pursuant to this subsection shall be immediately available and not subject to any restrictions or prior authorization requirements. Any prescription drug of a manufacturer or labeler that does not enter into such an agreement shall not be covered.

11. Dispensing of Drugs

Participating pharmacies are required to offer the consumer drugs from participating manufacturers when such products are available in the marketplace. A-rated generic drugs should be dispensed whenever possible.

12. Reimbursement

A. Claims must only be submitted to the Maine Rx Program if no other reimbursement option available. The Program provides access to discounted prescription drugs only when the individual does not have a comparable or superior prescription drug benefit plan.

B. The price charged to the eligible individual for all such prescription drugs will be a $3.35 dispensing fee plus the lowest of:

1. Federal Upper Limits (FUL) as defined in Chapter II, Section 80, Pharmacy Services, of the Medical Assistance Manual (MMAM);
2. Maine Maximum Allowable Cost (MMAC) as defined in Chapter II, Section 80, Pharmacy Services, of the MMAM;
3. Average Wholesale Price minus 6 percent (6%); or
4. Usual and Customary (U & C).

The Department assumes no liability for payments that are the responsibility of the consumer.

C. *Professional Fee*

For each prescription dispensed under this Program the pharmacist shall be reimbursed a $3.00 professional fee by the Department of Human Services.

D. The pharmacist shall clearly record on all claim forms for reimbursement for professional and dispensing fees under these rules all required information including patient name and identification number, date filled, drug name and drug type code, manufacturer, dosage form, strength, prescription number, estimated days supply, quantity, prescriber name and billing ID number and amount billed. The correct National Drug Code (NDC) must be used. Failure to use correct NDC code may result in a complete disallowance and/or recoupment for payments for incorrectly coded drugs.

E. *Claims Submission*

Participating pharmacies have the option to bill electronically or by paper claim.

1. *Electronic Format*. The electronic format shall be based on the same technical requirements as both the Maine Medicaid Point of Purchase (MEPOP) and Maine Low Cost Drugs for the Elderly and Disabled (DEL) prescription drug programs. This format shall comply with the National Council on Prescription Drug Programs (NCPDP) standards.

2. *Paper Claims*. No later than sixty (60) days after the date of service the completed forms shall be mailed to the Department's claim processing site. Failure to submit information in

a timely manner may result in nonpayment of claims.

13. Records for Audit Purposes

A. For each drug dispensed and for which a claim is submitted under the Program Agreement, the pharmacy shall maintain in permanent form an individual prescription, on the back of which shall be a record of each refill or, in compliance with State Pharmacy Law, a computerized record may be maintained. Said prescription shall be kept by the pharmacy either together with other prescriptions in a file of numerical or normally occurring order, or it may be maintained separately.

B. The pharmacy shall agree to submit to an audit, to be conducted by the Maine Department of Human Services or its designated agent, of records and transactions involving the dispensing of any and all prescription drugs under the Maine Rx Program. The pharmacy further agrees to furnish for review all materials and information regarding payment, including actual prescriptions, invoices for drug purchases, other appropriate documents, and any additional information which may be required by those authorized to determine compliance with this policy.

14. Fraud or Abuse

A. The State of Maine administers all of the funds for the Maine Rx Program and, therefore, pharmacies and participants are subject to Maine statutes pertaining to fraud.

B. Fraud also occurs when an eligible recipient allows, assists or conspires with an ineligible individual to obtain drugs under this Program.

C. All provisions relating to fraud and abuse and related sanctions outlined in Section I of the MMAM are applicable.

15. Prior Authorization

A drug manufacturer or labeler that sells prescription drugs in Maine through the Elderly Low-Cost Drug program (DEL) or any other publicly-supported pharmaceutical assistance program shall enter into a rebate agreement with the Department for this program. Drugs of non-participating drug manufacturers shall be reviewed by the Department as to the clinical appropriateness of prior authorization for those drugs under the Medicaid Program. Recommendations to prior authorize any of those drugs shall be referred to the Medicaid Drug Utilization Review Committee, for a final determination of whether those drugs should be prior authorized, in accordance with federal and State law. In all instances, Medicaid recipients shall be assured access to all medically necessary outpatient drugs.

16. Confidentiality

The Department shall protect the confidentiality of all information subject to confidentiality protection under State or federal law, rule or regulation.